EXHIBIT 1

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Attorneys for Plaintiff
Gen-Probe Incorporated

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. 99CV2668H AJB

FIRST AMENDED COMPLAINT FOR DECLARATORY RELIEF AND UNFAIR COMPETITION

PLAINTIFF GEN-PROBE ALLEGES:

INTRODUCTION

1. This action concerns the nature and scope of any obligation of plaintiff Gen-Probe Incorporated ("Gen-Probe") to make royalty payments to defendant Vysis, Inc. ("Vysis") pursuant to a patent license agreement between the parties ("the License") in light of the invalidity and non-infringement of United States Patent No. 5,750,338 ("the '338 patent") that is a subject of that License. As set forth below, Gen-Probe asks this court to declare the '338 patent invalid and further to declare that Gen-Probe's current and anticipated activities do not infringe any valid claims of the '338 patent. As a corollary to those declarations, Gen-Probe also asks this Court to declare its rights and obligations under the terms of the parties' License. Finally, Gen-Probe also seeks relief from Vysis' continuing acts of wrongful and unfair conduct with respect to the '338 patent.

THE PARTIES

2. Gen-Probe was founded in San Diego in 1984 as a small "start up" company, seeking to develop products based on the discoveries of a local research scientist. Over time, Gen-Probe became one of the largest biotechnology firms in San Diego. Gen-Probe now maintains its principal offices and research facilities at 10210 Genetic Center Drive in San Diego, where it employs over 500 scientists and staff. Gen-Probe is organized under the laws of the State of Delaware.

3. Gen-Probe is informed and believes that defendant Vysis, Inc. (hereinafter "Vysis" or "the defendant") is a corporation organized and incorporated under the laws of the State of Delaware. Gen-Probe is further informed and believes that Vysis maintains its principal place of business in Downers Grove, Illinois and that it is controlled by BP Amoco, Inc.

JURISDICTION AND VENUE

4. Counts One and Two of this Complaint seek declaratory relief under the Declaratory Judgment Act, Title 28, United States Code, Sections 2201 and 2202. This Court has subject matter jurisdiction of the claims asserted thereunder by reason of Title 28, United States Code, Sections 1331, 1338(a), 1338(b) and 1367.

5. Venue is proper in this District under Title 28, United States Code, Sections 1391(b) and 1400(b).

BACKGROUND

6. Living cells store genetic information in molecules of nucleic acid known as DNA. These molecules consist of long, thin, chain-like strands which, in turn, are usually found in the form of two tightly bound, complementary chains. DNA molecules retain their genetic information in the form of a genetic code. The information in the DNA determines the life processes of each organism. The information in the DNA is used to make related nucleic acid molecules called RNA that cells use to manufacture proteins.

7. Through the work of its scientists and staff, Gen-Probe has developed and continues to develop diagnostic tests that seek out the DNA or RNA of the infectious organisms. These types of tests are generally referred to as "genetic probes" or "nucleic acid tests" ("NAT"). Gen-Probe

now markets DNA probe products that test for a wide range of microorganisms that cause tuberculosis, strep throat, pneumonia, fungal infections and sexually transmitted diseases. Through the efforts of its scientists and staff, Gen-Probe has emerged as the recognized world leader in the development, manufacture and commercialization of diagnostic products based on its patented genetic probe technology. Gen-Probe has received over 40 FDA clearances and approvals for genetic probe tests to detect a wide range of microorganisms, including Chlamydia trachomatis, Mycobacterium tuberculosis and Neisseria gonorrhoeae.

8. Many human diseases are caused by bacterial or viral agents that invade living cells. Historically, the presence of these bacterial or viral agents was detected directly by time-consuming methods such as culture or indirectly through the detection of antibodies. Unfortunately, it takes time, sometimes weeks or months, to grow organisms in culture, and it usually takes months for the body to manufacture antibodies in sufficient amounts to reveal the presence of infectious agents. Consequently, these methods do not lend themselves to early detection of infection. NAT addresses this problem.

9. Among the disease detection technologies recently applied by Gen-Probe is its patented nucleic acid technology known as "Transcription-Mediated Amplification" ("TMA"). This technology enables Gen-Probe's NAT products to detect extraordinarily small quantities of the nucleic acids of infectious agents.

10. In September 1996, Gen-Probe received a $7.7 million grant from the National Institutes of Health to develop TMA-based nucleic acid tests to be used in screening donated blood for and human immunodeficiency virus (HIV), the causative agent of AIDS, and hepatitis C virus (HCV), which causes a severe form of hepatitis.

11. At the time of the NIH grant to Gen-Probe, donated blood was principally tested by procedures that detected the presence of antibodies to the viruses being screened. Due to the time it takes for the body to make antibodies after initial infection, donated blood may test negative for antibodies, yet still carry infectious viruses. This delay between the time of actual infection and the time that antibodies can first be detected is often known as the "window period." Reduction of this "window period" was a significant concern of the United States government and the primary focus

of the grant to Gen-Probe to develop NAT diagnostics for use in blood screening.

12. In fulfilling its obligations under the grant, Gen-Probe developed NAT tests to detect the DNA of HIV and hepatitis C in blood. Through the use of its NAT test, Gen-Probe believes that researchers and medical personnel may rapidly and *directly* detect the presence of genetic material of viruses like HIV and HCV more accurately and without the complications and delay associated with conventional *indirect* tests. As such, Gen-Probe believes that its new test may significantly reduce the "window period" for detection of these extremely harmful viral agents and resulting diseases.

13. Final development of the NAT tests for blood screening in the United States is now taking place in testing conducted by the American Red Cross, America's Blood Centers, and others. ("A Purity Quest; Local Biotech's Ultra-Sensitive Blood Screening Could Cut Risk of AIDS, Hepatitis," *San Diego Union*, March 25, 1999, page C-1.) Use of the tests in the United States is made pursuant to an Investigational New Drug Application filed with the United States Food and Drug Administration. In blood tested by the American Red Cross, Gen-Probe's products have detected hepatitis C and HIV which escaped detection by prior methods. ("New Blood Screening Finds Virus Others Missed; Experimental Test Turns Up Hepatitis C In Donated Blood," *San Diego Union*, April 2, 1999, page B-2.)

14. On September 21, 1999, the French Ministry of Health approved the sale of the Gen-Probe blood screening tests in France. Gen-Probe anticipates approval of its tests for us in Australia in early 2000.

15. Gen-Probe has entered into an agreement with Chiron Corporation ("Chiron") of Emeryville, California, with respect to the development, manufacture, and distribution of blood screening products. Gen-Probe is also a party to an agreement with Bayer Corporation ("Bayer") of Emeryville, California with respect to the development, manufacture, and distribution of clinical diagnostic products for the detection of HIV and hepatitis C, among other pathogens.

16. Gen-Probe anticipates that additional clinical trials in the United States of its HIV/HCV tests for use in blood screening and in clinical diagnostics will commence in the first part of 2000. Gen-Probe anticipates the conclusion of those clinical trials, and the initiation of

commercial sales in the United States of kits containing its HIV/HCV blood screening test, during 2000.

17. All of the Gen-Probe products are manufactured in San Diego, California.

THE '338 PATENT

18. Gen-Probe is informed and believes that on or about May 12, 1998, the United States Patent and Trademark Office issued United States Patent No. 5,750,338 ("the '338 patent") based upon Patent Application No. 238,080 filed on May 3, 1994.

19. Gen-Probe is informed and believes that defendant Vysis claims to be the owner, by assignment, of the entire right, title and interest of the '338 patent. The claims of the '338 patent purport to relate to assays and probes for polynucleotide molecules such as DNA and RNA.

20. In early 1999, Vysis informed Gen-Probe that it believed that the '338 patent "applied" to Gen-Probe's NAT blood screening tests for HIV and HCV. Following further discussions and to avoid any complications in Gen-Probe's plans for commercial deployment of its NAT test kits, as of June 22, 1999 Gen-Probe obtained a license ("the License") from Vysis under the '338 patent. Gen-Probe also obtained options to the License for its relationships with Chiron and Bayer.

21. Under the terms of the License, Vysis requires Gen-Probe (and its allied parties if the options are exercised) to make significant financial payments to Vysis as royalties on the sale of any product covered by any valid claims of the '338 patent.

22. Notwithstanding the existence of the License, and as further alleged herein, Gen-Probe believes that the claims of '338 patent are invalid in all material respects. Furthermore, Gen-Probe believes that its NAT blood screening tests do not infringe any valid claim of the '338 patent. As such, Gen-Probe disagrees with Vysis' contention that the claims of the '338 patent "apply" to Gen-Probe's activities and contemplated products. For these same reasons, Gen-Probe contends that it has no obligation to make any royalty payments to Vysis with respect to its present products and activities and any contemplated products and activities that Vysis may later claim infringe the claims of the '338 patent.

23. Gen-Probe has communicated to Vysis its belief that the claims of the '338 patent

are invalid. In support of that belief, Gen-Probe has provided Vysis with information that demonstrates that the claims of the '338 patent are invalid. Gen-Probe has also advised Vysis of its belief that its NAT test kits for use in detecting HCV and HIV in the Nation's blood supply do not and will not infringe any valid claims of the '338 patent.

24. Notwithstanding its receipt of the foregoing information, Vysis persists in its assertion that the claims of the '338 patent are valid and enforceable and that Gen-Probe is obligated to make royalty payments in accordance with the terms of the License.

25. Based upon a long history of litigation between Gen-Probe and Vysis and its affiliates, Gen-Probe reasonably anticipates that should it fail to pay royalties pursuant to the License, Vysis will aggressively attempt to enforce its perceived rights under both the License and the '338 patent by terminating the License and by initiating litigation against Gen-Probe, its allied parties, and customers.

26. An actual case or controversy exists between Gen-Probe and Vysis concerning the validity and infringement of the '338 patent and Gen-Probe's rights and obligations under the License. The determination of the issues presented in this complaint will inure to the greater public benefit and good.

COUNT ONE

NON-INFRINGEMENT OF THE '338 PATENT

27. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

28. Gen-Probe's NAT test kits for use in detecting HCV and HIV in the Nation's blood supply do not and will not infringe any valid claims of the '338 patent.

COUNT TWO

INVALIDITY OF THE '338 PATENT

29. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

30. The claims of the '338 patent are invalid by reason of one or more provisions of Title 35 of the United States Code.

COUNT THREE

DECLARATORY RELIEF

31. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

32. An actual controversy has arisen and now exists concerning the rights and obligations of Gen-Probe pursuant to the terms of the parties' License. Those disputes arise from and their resolution depends upon the federal patent laws.

33. Gen-Probe seeks a declaration of its rights and obligations under the License, particularly in light of the invalidity and non-infringement of the '338 patent and defendant's acts of unfair competition as alleged herein.

COUNT FOUR

UNFAIR COMPETITION

34. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 33 of this complaint.

35. Vysis knows or should know the underlying facts establishing the invalidity of the claims of the '338 patent. In continuing to enforce the claims of the '338 patent, Vysis has acted and continues to act unfairly, inequitably and in bad faith. In addition, Vysis' actions constitute unlawful, unfair or fraudulent business practices under California Business & Professions Code Sections 17200, *et seq.*

36. By reason of the aforementioned acts of unfair competition and unlawful, unfair and fraudulent business practices, Gen-Probe is entitled to damages, as established at time of trial, restitution and injunctive relief.

WHEREFORE, Gen-Probe prays as follows:

1. For declarations:

a. That Gen-Probe's products do not and will not infringe any valid claims of '338 patent;

b. That the claims of the '338 patent are invalid; and

c. Of Gen-Probe's rights and obligations under the parties' License;

2. For a preliminary and permanent injunction enjoining and restraining defendant, its respective officers, agents, servants, employees and attorneys, and all persons acting in concert with them, and each of them:

a. From making any claims to any person or entity that Gen-Probe's products infringe the '338 patent;

b. From interfering with, or threatening to interfere with the manufacture, sale, license, or use of Gen-Probe's products by Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns, and others; and

c. From instituting or prosecuting any lawsuit or proceeding, placing in issue the right of Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns, and others to make, use or sell Gen-Probe's products;

3. For recovery of Gen-Probe's damages, as proven at time of trial, and restitution of any sums by which Vysis has been unjustly enriched;

4. For recovery of Gen-Probe's attorneys' fees and costs of suit incurred herein; and

5. For such other and further relief as the Court may deem just and proper.

Dated: January 25 1999

COOLEY GODWARD LLP
STEPHEN P. SWINTON (106398)
JAMES DONATO (146140)

By: _____
Stephen P. Swinton

Attorneys for Plaintiff
Gen-Probe Incorporated

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Attorneys for Plaintiff
Gen-Probe Incorporated

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. 99CV2668H AJB

PROOF OF SERVICE BY MAIL

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I, Alison J. Lyman, hereby declare:

I am employed in the City of San Diego, County of San Diego, California in the office of a member of the bar of this court at whose direction the following service was made. I am over the age of eighteen years and not a party to the within action. My business address is Cooley Godward LLP, 4365 Executive Drive, Suite 1100, San Diego, California 92121-2128. I am personally and readily familiar with the business practice of Cooley Godward LLP for collection and processing of correspondence for mailing with the United States Postal Service, pursuant to which mail placed for collection at designated stations in the ordinary course of business is deposited the same day, proper postage prepaid, with the United States Postal Service.

On January 26, 2000, I served: **FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** on the interested parties in this action by placing a true copy thereof, on the above date, enclosed in a sealed envelope, following the ordinary business practice of Cooley Godward LLP, for collection and mailing in the United States mail addressed as follows:

John H. L'Estrange, Jr. Esq.
Wright and L'Estrange
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Palo Alto, CA 94304
Tel: (650) 849-6600
Fax: (650) 849-6666
Attorneys for Vysis, Inc.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on January 26, 2000, at San Diego, California.

Alison J. Lyman

EXHIBIT 2

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Attorneys for Plaintiff
Gen-Probe Incorporated

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. 99cv2668 H (AJB)

GEN-PROBE INCORPORATED'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS TO VYSIS, INC.

PROPOUNDING PARTY: **GEN-PROBE INCORPORATED**

RESPONDING PARTY: **VYSIS, INC.**

SET NUMBER: **ONE**

Pursuant to Federal Rule of Civil Procedure 34(a)(1), Plaintiff Gen-Probe Incorporated ("Gen-Probe") hereby requests that all documents and tangible things described below be produced for its inspection and/or copying by Gen-Probe in accordance with the Definitions and Instructions set forth below on March 6, 2000 at 10:00 a.m. at the offices of its counsel, Cooley Godward LLP, 4365 Executive Drive, 11th Floor, San Diego, California 92121.

I. DEFINITIONS AND INSTRUCTIONS.

1. VYSIS, YOU, and YOUR mean defendant Vysis, Inc, its directors, officers, employees, attorneys, accountants, consultants, representatives, agents, any parent corporations,

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subsidiaries, divisions, successors in interest, any partnerships or joint ventures to which it is a party, and/or other PERSONS acting on its behalf.

2. DOCUMENT is used in its broadest sense, and has the same meaning as "documents" as defined in Federal Rule of Civil Procedure 34(a). As used herein, DOCUMENTS includes "things."

3. COMMUNICATION means any transmission of information from one PERSON or entity to another by any means.

4. PERSON means any natural person and any other cognizable entity, including (without limitation) corporations, proprietorships, partnerships, joint ventures, consortiums, clubs, associations, foundations, governmental agencies or instrumentalities, societies and orders.

5. '338 PATENT means United States Patent No. 5,750,338, as well as any and all divisionals, counterparts, continuations, continuations-in-part, or parents thereof, the applications from which any of the foregoing resulted, and any and all other related U.S. and foreign applications.

6. LICENSE means that certain Nonexclusive License Agreement Under Vysis' Collins Patents between Gen-Probe and VYSIS, dated June 22, 1999.

7. Wherever used herein, the singular shall include the plural and the plural shall include the singular.

8. You are to produce the original and each non-identical copy of each DOCUMENT or other tangible thing requested herein which is in your possession, custody or control.

9. If you do not produce any DOCUMENT because it is stored electronically or by means of other media, identify such DOCUMENT by the subject matter of the DOCUMENT and the place(s) where such DOCUMENT is maintained, and provide a suitable method for retrieving the DOCUMENT.

10. If a request is silent as to the time period for which production of DOCUMENTS and things is sought, you are to produce all DOCUMENTS originated in whole or in part and of all things within your possession, custody, or control at any time during the period December 21, 1987 through the date of your production.

II. DOCUMENTS TO BE PRODUCED.

REQUEST FOR PRODUCTION NO. 1:

All DOCUMENTS called for by Federal Rule of Civil Procedure Rule 26(a)(1)(B).

REQUEST FOR PRODUCTION NO. 2:

All DOCUMENTS identified in, or relied upon by YOU while preparing, YOUR responses to Gen-Probe Incorporated's First Set of Interrogatories to Vysis, Inc.

REQUEST FOR PRODUCTION NO. 3:

All DOCUMENTS that constitute, evidence or refer to any method or kit for amplifying and/or detecting a target polynucleotide contained in a sample.

REQUEST FOR PRODUCTION NO. 4:

All DOCUMENTS that constitute, evidence or refer to a method or kit for amplifying and/or detecting a target polynucleotide contained in a clinical sample.

REQUEST FOR PRODUCTION NO. 5:

All DOCUMENTS that constitute, evidence or refer to the research and/or development of the methods or kits claimed in the '338 PATENT.

REQUEST FOR PRODUCTION NO. 6:

All DOCUMENTS that constitute, evidence or refer to any and all prior art relevant to the '338 PATENT, including but not limited to any brochures or samples, patents and publications, dated prior to May 3, 1994.

REQUEST FOR PRODUCTION NO. 7:

All DOCUMENTS that constitute, evidence or refer to the '338 PATENT.

REQUEST FOR PRODUCTION NO. 8:

All DOCUMENTS that constitute, evidence or refer to any experiments or research by or on behalf of Mark L. Collins, Donald N. Halbert, Walter King, Jonathan M. Lawrie, Bruce P. Neri, John S. Curtis, and/or Danahey Ryan, concerning any method for amplifying a target polynucleotide contained in a sample and/or sample medium including but not limited to any (1) theses, (2) dissertations, (3) journal articles, (4) lab notebooks, (5) memoranda, (6) handwritten notes, or (7) oral presentation materials.

REQUEST FOR PRODUCTION NO. 9:

All DOCUMENTS that constitute, evidence or refer to any experiments or research by or on behalf of Mark L. Collins, Donald N. Halbert, Walter King, Jonathan M. Lawrie, Bruce P. Neri, John S. Curtis, and/or Danahey Ryan, concerning any method for detecting a target polynucleotide contained in a sample, and/or sample medium, including but not limited to any (1) theses, (2) dissertations, (3) journal articles, (4) lab notebooks, (5) memoranda, (6) handwritten notes, or (7) oral presentation materials.

REQUEST FOR PRODUCTION NO. 10:

All DOCUMENTS that constitute, evidence or refer to any experiments or research by or on behalf of Mark L. Collins, Donald N. Halbert, Walter King, Jonathan M. Lawrie, Bruce P. Neri, John S. Curtis, and/or Danahey Ryan, concerning any kit for detecting a target polynucleotide contained in a sample, including but not limited to any (1) theses, (2) dissertations, (3) journal articles, (4) lab notebooks, (5) memoranda, (6) handwritten notes, or (7) oral presentation materials.

REQUEST FOR PRODUCTION NO. 11:

All DOCUMENTS that constitute, evidence or refer to any experiments or research by or on behalf of Mark L. Collins, Donald N. Halbert, Walter King, Jonathan M. Lawrie, Bruce P. Neri, John S. Curtis, and/or Danahey Ryan, concerning any kit for amplifying a target polynucleotide contained in a sample, including but not limited to any (1) theses, (2) dissertations, (3) journal articles, (4) lab notebooks, (5) memoranda, (6) handwritten notes, or (7) oral presentation materials.

REQUEST FOR PRODUCTION NO. 12:

All DOCUMENTS that constitute, evidence or refer to the work reported in each of the examples of the '338 PATENT.

REQUEST FOR PRODUCTION NO. 13:

All DOCUMENTS provided by YOU and/or Mark L. Collins, Donald N. Halbert, Walter King, Jonathan M. Lawrie, Bruce P. Neri, John S. Curtis, and/or Danahey Ryan to the patent lawyers who prepared the applications which led to issuance of the '338 PATENT, and all technical

correspondence and COMMUNICATIONS between the inventors and their patent attorneys concerning the preparation of such applications.

REQUEST FOR PRODUCTION NO. 14:

All DOCUMENTS that constitute, evidence or refer to any experimental results, or to any other information submitted to the U.S. Patent and Trademark Office in connection with the prosecution of the '338 PATENT, or information reported to any patent office or other government agency in connection with the prosecution of any related patents or applications, including, but not limited to, (1) records of all work performed, (2) all materials and methods used, and (3) all data in connection with any experiments performed to obtain the results described in such submissions.

REQUEST FOR PRODUCTION NO. 15:

All DOCUMENTS that constitute, evidence or refer to declarations or affidavits submitted to the U.S. patent and Trademark Office in connection with the prosecution of the '338 PATENT.

REQUEST FOR PRODUCTION NO. 16:

All DOCUMENTS that constitute, evidence or refer to the following patent applications:

a. U.S. Patent Application Serial No. 238,080, filed May 3, 1994;

b. U.S. Patent Application Serial No. 400,657, filed March 8, 1995

c. U.S. Patent Application Serial No. 257,469, filed June 8, 1994

d. U.S. Patent Application Serial No. 124,826, filed September 21, 1993

e. U.S. Patent Application Serial No. 946,749, filed September 17, 1992

f. U.S. Patent Application Serial No. 648,468, filed January 31, 1991

g. U.S. Patent Application Serial No. 644,967, filed January 22, 1991

h. U.S. Patent Application Serial No. 136,920, filed December 21, 1987

i. U.S. Patent Application Serial No. 922,155, filed October 23, 1986

j. U.S. Patent Application Serial No. 944,505, filed September 14, 1992

REQUEST FOR PRODUCTION NO. 17:

All DOCUMENTS, including but not limited to patents and printed publications, that illustrate and/or describe the subject matter of the '338 PATENT.

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REQUEST FOR PRODUCTION NO. 18:

All DOCUMENTS that constitute, evidence or refer to any and all uses by any PERSON of any product or method for the amplification and/or detection of a target polynucleotide contained in a sample prior to May 3, 1994.

REQUEST FOR PRODUCTION NO. 19:

All DOCUMENTS that constitute, evidence or refer to sales, offers for sale, or disclosures by any PERSON of any product or method for the amplification and/or detection of a polynucleotide contained in a sample prior to May 3, 1994.

REQUEST FOR PRODUCTION NO. 10:

All DOCUMENTS that constitute, evidence or refer to any and all uses by any PERSON of the invention of the '338 PATENT with the permission of Mark. L. Collins, Donald N. Halbert, Walter King, and/or Jonathan M. Lawrie prior to May 3, 1994, and any payments made to Mark. L. Collins, Donald N. Halbert, Walter King, and/or Jonathan M. Lawrie for such use.

REQUEST FOR PRODUCTION NO. 21:

All DOCUMENTS that constitute, evidence or refer to the conception of the subject matter claimed in the '338 PATENT, including but not limited to laboratory notebooks, invention disclosures or records of invention, periodic reports, publications, and correspondence.

REQUEST FOR PRODUCTION NO. 22:

All DOCUMENTS that constitute, evidence or refer to the reduction to practice of the subject matter claimed in the '338 PATENT, including but not limited to laboratory notebooks, invention disclosures or records of invention, periodic reports, publications, and correspondence.

REQUEST FOR PRODUCTION NO. 23:

All DOCUMENTS that constitute, evidence or refer to the research and development of the subject matter claimed in the '338 PATENT prior to May 3, 1994.

REQUEST FOR PRODUCTION NO. 24:

All DOCUMENTS that constitute, evidence or refer to any patent application filed in the United States by YOU or by Mark L. Collins, Donald N. Halbert, Walter King, Jonathan M.

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Lawrie, Bruce P. Neri, John S. Curtis, and/or Danahey Ryan that describes or claims a method or kit amplification and/or detection, of a target polynucleotide contained in a sample.

REQUEST FOR PRODUCTION NO. 25:

All DOCUMENTS that constitute, evidence or refer to opinions or other COMMUNICATIONS by or to YOU, or by or to any other PERSON, on the issues of infringement, validity, or enforceability of the '338 PATENT, or any other issue relating to the '338 PATENT.

REQUEST FOR PRODUCTION NO. 26:

All DOCUMENTS discussing or analyzing the '338 PATENT and the applications leading thereto, including but not limited to (1) all DOCUMENTS discussing or analyzing the (a) strength, (b) coverage, (c) legal significance, or (d) business significance of the '338 PATENT; (2) the applications leading thereto; or (3) any foreign counterpart patents and applications thereof.

REQUEST FOR PRODUCTION NO. 27:

All DOCUMENTS that constitute, evidence or refer to any license agreement that YOU have entered into, and any royalty that YOU receive or pay or have agreed to receive or pay, with respect to the manufacture, sale, or use of the subject matter claimed in the '338 PATENT.

REQUEST FOR PRODUCTION NO. 28:

All DOCUMENTS that constitute, evidence or refer to any discussion or offer made by YOU to another, or any request or refusal by another, to take a license under the '338 PATENT.

REQUEST FOR PRODUCTION NO. 29:

All DOCUMENTS sufficient to describe assays or kits for the amplification and/or detection of a target polynucleotide contained in a sample, made, sold or offered for sale by YOU or by any of Your licensees that YOU contend are within the claims of the '338 PATENT.

REQUEST FOR PRODUCTION NO. 30:

A sample of each of the assays or kits for the detection of a target polynucleotide contained in a sample made, sold or offered for sale by YOU or by any of YOUR licensees that YOU contend are within the claims of the '338 PATENT.

REQUEST FOR PRODUCTION NO. 31:

All DOCUMENTS submitted to the Food and Drug Administration or other governmental

regulatory agency for the purpose of obtaining licensing or approval of products that YOU contend are within the claims of the '338 PATENT.

REQUEST FOR PRODUCTION NO. 32:

All DOCUMENTS that constitute, evidence or refer to efforts by others to invent the subject matter claimed by the '338 PATENT at any time prior to May 3, 1994.

REQUEST FOR PRODUCTION NO. 33:

All DOCUMENTS that constitute, evidence or refer to any ownership interest formerly possessed, now possessed, or to be acquired by any PERSON, entity, or institution in the subject matter claimed in the '338 PATENT, whether arising by virtue of inventorship, assignment, license, security interest, lien, or any other direct or beneficial interest, including but not limited to all DOCUMENTS that constitute, evidence or refer to any actual or proposed assignment, license, or other disposition of right, title, or interest in the subject matter of the '338 PATENT.

REQUEST FOR PRODUCTION NO. 34:

All DOCUMENTS that constitute, evidence or refer to COMMUNICATIONS between YOU and present or former Gen-Probe employees, agents or representatives regarding the '338 PATENT or methods for amplifying and/or detecting target polynucleotides.

REQUEST FOR PRODUCTION NO. 35:

All DOCUMENTS that constitute, evidence or refer to YOUR document retention or destruction policies.

REQUEST FOR PRODUCTION NO. 36:

Corporate organization charts sufficient to identify YOUR organization structure generally and as it relates to the following functions as they relate to the subject matter claimed in the '338 PATENT: (a) research and development; (b) patents; (c) licensing; (d) manufacturing; (e) distribution; (f) marketing and sales; and (g) strategic planning.

REQUEST FOR PRODUCTION NO. 37:

All publications authored by each PERSON that YOU intend to offer as an expert witness and all DOCUMENTS that YOUR or any PERSON acting on YOUR behalf has shown or otherwise made the contents of available to any such expert.

REQUEST FOR PRODUCTION NO. 38:

All publications authored or co-authored by YOUR, Mark L. Collins, Donald N. Halbert, Walter King, Jonathan M. Lawrie, Bruce P. Neri, John S. Curtis, and/or Danahey Ryan that refer to or evidence a method or kit for the amplification and/or detection of a target polynucleotide contained in a sample.

REQUEST FOR PRODUCTION NO. 39:

All DOCUMENTS that constitute, evidence or refer to speeches or other presentations by YOU, Mark L. Collins, Donald N. Halbert, Walter King, Jonathan M. Lawrie, Bruce P. Neri, John S. Curtis, and/or Danahey Ryan, relating to a method or kit for the amplification and/or detection of a target polynucleotide contained in a sample including but not limited to any files or notes about such speeches or presentations, any and handouts given to the persons to which the speech or presentation was made.

Dated: February 3, 2000

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. 99 CV 2668H AJB

MEMORANDUM OF POINTS AND AUTHORITIES OF GEN-PROBE INCORPORATED IN RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6)

Date: April 24, 2000
Time: 10:30 a.m.
Dept.: Courtroom 1

Trial Date: Not Yet Set

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I. INTRODUCTION.

In this action, plaintiff Gen-Probe Incorporated seeks a declaration that United States Patent Number 5,750,338 (the "'338 patent") is invalid. Gen-Probe also alleges that defendant Vysis, Inc. has committed unfair competition by enforcing the '338 patent against Gen-Probe in bad faith, while knowing the patent to be invalid.

In response to Gen-Probe's complaint, Vysis has declared to the United States Patent and Trademark Office (the "Patent Office") that the '338 patent is "partly inoperative" due to an "error" in the prosecution of the patent. (*See* Page 127 of Exhibit E to Declaration of John L'Estrange In Support of Vysis' Motion ("Vysis Exh. ___").) Rather than submit the existing patent to scrutiny in this Court, Vysis seeks to change the claims of the patent through a "reissue" proceeding in the Patent Office. By federal regulation, the reissue proceeding will be conducted *ex parte*, and Gen-Probe will be precluded from participating in that proceeding in any meaningful fashion.

Gen-Probe will be prejudiced by any delay in the adjudication of its claims until after the reissue proceeding is completed. *If* the Court elects to delay further proceedings in this case while Vysis seeks to change the patent in the Patent Office, the Court should impose conditions that are adequate to protect Gen-Probe against the prejudice that it will suffer as a result of the delay. Such conditions are essential, and the Court should impose a stay *only* in conjunction with the imposition of conditions required by equity and fairness. Furthermore, any stay of this case should be complete – it should not be a partial, one-sided stay that permits Vysis alone to keep this action alive for the sole purpose of obtaining unilateral discovery.

Finally, the Court should deny Vysis' alternative motion to dismiss Gen-Probe's fourth claim of relief for unfair competition. According to Vysis, the mere existence of a license agreement for the '338 patent insulates Vysis from any claim of unlawful, unfair or fraudulent business practices under California law. Vysis' argument ignores the fact of Vysis' bad faith enforcement of the patent, through the license agreement and other conduct. Vysis' argument also ignores decisions by the United States Court of Appeals for the Federal Circuit that confirm the vitality of unfair competition claims in the circumstances alleged in the First Amended Complaint.

II. FACTUAL BACKGROUND.

In light of the procedural posture of this case, the Court must accept as true the facts that Gen-Probe asserts in its operative complaint. *E.g., Cooper v. Pickett*, 137 F.3d 616, 623 (9th Cir. 1998); *NL Industries, Inc. v. Kaplan*, 792 F.2d 896, 898 (9th Cir. 1986).

A. The Parties

1. Gen-Probe Incorporated.

Gen-Probe was founded in San Diego in 1984 as a small "start up" company seeking to develop products based on the discoveries of a local research scientist. Over time, Gen-Probe has become one of the largest biotechnology firms in San Diego. Gen-Probe now maintains its principal offices and research facilities at 10210 Genetic Center Drive in San Diego, where it employs over 600 scientists and staff.

Gen-Probe has developed and continues to develop diagnostic tests that seek to detect the DNA or RNA of infectious organisms. These types of tests are generally referred to as "genetic probes" or nucleic acid tests ("NAT"). Gen-Probe now markets genetic probe products that test for a wide range of microorganisms that cause tuberculosis, strep throat, pneumonia, sexually transmitted diseases, and fungal infections.

2. Vysis, Inc.

Defendant Vysis, Inc. is a public corporation that maintains its principal place of business in Downers Grove, Illinois. It is a subsidiary of BP Amoco plc. Vysis claims that it is the assignee of the '338 patent. While Vysis markets numerous products, it has never been profitable.

B. Gen-Probe's NAT Test Kits.

In 1996, Gen-Probe received a grant of $7.7 million from the National Institutes of Health to develop NAT tests to detect HIV and hepatitis C in blood donated for transfusion. At the time of the grant, existing screening tests relied upon the detection of antibodies to the viruses when those antibodies were produced by the immune system. Significantly, a "window" period exists between the time a person is first infected with a virus, such as HIV or hepatitis C, and the time that the body first produces antibodies to the disease. The NIH-funded research was intended

to expedite development of NAT tests that could rapidly and directly detect the HIV and HCV viruses themselves, even before the body first produced antibodies to the viruses. These tests would thus reduce the "window" period in which infected blood might be unknowingly transfused.

Gen-Probe succeeded in developing the NAT tests sought by the NIH. Gen-Probe's tests have been in use by the American Red Cross and America's Blood Centers since March 1999, pursuant to an Investigational New Drug ("IND") application.[1] ("A Purity Quest; Local Biotech's Ultra-Sensitive Blood Screening Could Cut Risk of AIDS, Hepatitis," *San Diego Union*, March 25, 1999, page C-1). In blood tested by the American Red Cross, Gen-Probe's products have detected hepatitis C and HIV in donated blood after the viruses escaped detection by the prior antibody-based methods. ("New Blood Screening Finds Virus Others Missed; Experimental Test Turns Up Hepatitis C in Donated Blood," *San Diego Union*, April 2, 1999, page B-2.)

Further clinical trials in the United States of the HIV/HCV blood screening tests will commence this month. Commercial sales in the United States of kits containing its HIV/HCV blood-screening test will likely begin during 2000. Gen-Probe has already received regulatory approval of the tests in France and Australia.

C. The '338 patent and the prosecution history.

This litigation concerns the validity of the '338 patent and whether Gen-Probe's products and activities infringe that patent. The specification of the '338 patent purports to teach a method that combines isolation of a target DNA in a step known as "target capture", and a subsequent process in which many copies of that DNA are made (the "amplification" step).

The '338 patent prosecution history began on October 23, 1986 with the filing of United States Patent Application Number 922,155 ("the '155 Application"). This application claimed a method for target capture, but it did not disclose the combination of target capture and amplification that the '338 patent claims. A continuation-in-part application of the '155 Application, United States Patent Application Number 136,920 was filed on December 21, 1987

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[1] Because of the importance of the NAT tests, they are regarded by the FDA as a "drug" rather than as an ordinary diagnostic product

and this application is the first the Collins' family of patents to disclose target capture couples with target amplification.

The '338 patent prosecution history began on October 23, 1986 with the filing of United States Patent Application Number 922,155. This application claimed a method for target capture, but it did not disclose the combination of target capture and amplification that the '338 patent claims.

The prosecution history of the patent is extraordinary. The original application eventually led, through a series of at least six subsequent applications over a period of almost twelve years, to the issuance of the '338 patent in May 1998. In the course of prosecution, Vysis several times abandoned its applications, and was forced to petition the Patent Office to revive them.

D. The History Of This Litigation.

Almost immediately after issuance of the '338 patent, through a thinly-veiled threat of an infringement suit, Vysis asserted the '338 patent against Gen-Probe's NAT kits. (First Amended Complaint, ¶ 20, Exh. 1 To Notice of Lodgment ("NOL")) On June 22, 1999, in order to avoid last-minute complications in the introduction of those kits, Gen-Probe signed a license to the '338 patent. (Vysis Exh. D.) Pursuant to the terms of the license, Gen-Probe must pay royalties to Vysis until such time as the patent is declared invalid. However, Gen-Probe has no obligation to pay royalties unless its products are covered by the '338 patent. *Id.*

This suit commenced on December 22, 1999, when Gen-Probe filed a complaint in the United Stated District Court for the Southern District of California. (Declaration of Patrick M. Maloney ("Maloney Decl."), ¶ 2.) Gen-Probe sought a declaration that the '338 patent is invalid and a declaration that Gen-Probe's products and activities, namely its NAT test kits, do not infringe the '338 patent.

On January 6, 2000, Gen-Probe informally disclosed to Vysis several prior art references that Gen-Probe believed render the '338 patent invalid because the technology claimed in the patent was anticipated by or obvious in light of the work of others. (Vysis Exh. B.) Vysis responded on January 19, 2000 that it believed that the references did not effect the validity of the '338 patent. (Vysis Exh. C.)

On January 26, 2000, before Vysis responded to the Complaint, Gen-Probe filed and served on Vysis a First Amended Complaint that included the prior invalidity and non-infringement counts and also added counts for a declaration that Gen-Probe is not obligated to make royalty payments to Vysis pursuant to the license concerning the '338 patent and for violations of the California Unfair Business Practices Act, California Business and Professions Code §17200 *et. seq.* (the Unfair Competition Claim). (Maloney Decl., ¶ 3.) In the unfair competition claim, Gen-Probe asserts that Vysis has committed acts of unfair competition by persisting to enforce the '338 patent even though Vysis knows that the patent is invalid.

Notwithstanding Vysis' January 19 response to the contrary, on March 8, 2000, Vysis apparently filed a reissue application with the Patent and Trademark Office, declaring the '338 patent to be "partially inoperative." (Vysis Exh. F.) Contrary to the express requirements of the Patent Office (Manual of Patent Examination Procedures ("MPEP") § 1442.04), Vysis failed to disclose in its reissue application that the patent that it seeks to amend is the subject of pending litigation.

After the parties served one another with initial rounds of discovery, the parties agreed to stay the discovery, and Vysis responded to the First Amended Complaint on March 9, 2000 by filing the instant motion for a stay, which alternatively requests that Gen-Probe's unfair competition claim be dismissed. (Maloney Decl. ¶¶ 4-8.) The parties recently again stayed all discovery pending the resolution of the instant motion. (*Id.*, ¶ 9.)

III. IF THE COURT ELECTS TO IMPOSE A STAY, IT SHOULD IMPOSE CONDITIONS THAT WILL ENSURE THE PROMPT RESOLUTION OF THE PATENT OFFICE PROCEEDINGS AND PROTECT GEN-PROBE FROM THE PREJUDICIAL EFFECTS OF THE DELAY

In response to the complaint in this case, Vysis has elected to declare the '338 patent "partially inoperative" (Vysis Exh. E, p. 127) and now seeks to change the patent before submitting it to scrutiny by this Court. In considering Vysis' motion for a stay, the Court should evaluate and balance (1) the benefits that may flow from the reissue process, (2) the hardships and prejudice that staying the litigation while reissue is pending will cause the parties, and (3) how far the litigation has proceeded. *Xerox v. 3Com Corp.*, 69 F.Supp.2d 404, 406-407 (W.D.N.Y. 1999). Indeed, despite the perceived advantages of a stay pending a Patent Office determination, several

courts have denied a stay where the stay would cause undue prejudice or present a clear tactical disadvantage to the non-moving party. *E.g., GPAC, Inc. v. D.W.M. Enterprises, Inc,* 144 F.R.D. 60 (D.N.J. 1992); *Freeman v. Minnesota Mining & Mfg, Co.,* 661 F. Supp. 886, 888 (D. Del. 1987).

A. A stay will likely delay resolution of this case by over a year.

If a stay is granted pending the completion of the reissue proceeding, significant delay in adjudicating Gen-Probe's claims will inevitably result. Gen-Probe will be prejudiced by that delay.

To begin with, Vysis' suggestion that its reissue proceedings will be conducted in an expeditious manner greatly overstates the speed with which the Patent Office disposes of reissue proceedings in general and, given the conduct of Vysis thus far, the speed with which it is likely to dispose of Vysis' application in particular. For example, on average, even though the Patent Office deems reissue proceedings "special," it still requires in excess of one year to dispose of such matters in the Patent Office. According to the 1998 Patent and Trademark Office Annual Report – Fiscal Year 1998: A Patent And Trademark Office Review -- the average time in 1998 to process a utility, plant, or reissue application was 16.9 months, and the Patent Office *hoped* to reduce this to an *average* of 10 months by 2000. (NOL, Exh. 2, p. 18.) Moreover, the Manual of Patent Examining Procedures, in section 1442.01, permits the Patent Office to grant the applicant an extension of time within which to respond to any office action that is long and complex. Given the '338 patent's lengthy and tortured prosecution history, it is not unreasonable to assume that the reissue proceedings will take longer than average.[2]

The evidence already suggests that Vysis is not motivated to resolve the pending reissue proceedings as quickly as its moving papers might suggest. Vysis has failed to comply with Section 1442.04 of the MPEP. This section required Vysis to disclose to the Patent Office in its

[2] One reason for that delay is that reissue applicants may file continuation applications. Thus, although the time for any individual response may be limited, a reissue applicant such as Vysis may delay the ultimate proceedings endlessly through continuation practice and filibuster. *Cf. United Sweetener USA, Inc. v. Nutrasweet Co.*, 766 F. Supp. 212, 218-219 (D. Del. 1991) (court concerned that litigants would use Patent Office appeals following reexamination to its tactical advantage).

initial reissue application the fact that the '338 patent is the subject of litigation. Among other things, that disclosure would prompt expediting processes within the Patent Office (albeit subject to the potential delay and filibuster of continuation practice).[3]

B. Reissue will not dispose of this litigation.

Implicit in Vysis' motion for a stay is the suggestion that its efforts to obtain reissue of the '338 patent will dispose of this litigation. This suggestion is without any basis. As discussed below, when the stay terminates, this case will return to the very same posture that it was in when Vysis filed its reissue application.

Vysis contends that the reissue proceeding will somehow expedite the resolution of this case upon the termination of the stay and the resumption of proceedings in this Court. In fact, the only clear result of Vysis' belated reissue application will be delay in the adjudication of the issues raised by the complaint in this case.

Contrary to Vysis' express suggestion, the fact that the patent will have undergone further *ex parte* examination by the Patent Office in the course of the reissue process will *not* change the scope of review in this Court when the reissue proceeding is complete. *T.J. Smith and Nephew Ltd. v. Consolidated Medical Equipment, Inc.*, 821 F.2d 646, 648 (Fed. Cir. 1987) ("The presumption of validity ... is not 'strengthened' by reissue"); *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549 (Fed. Cir. 1985) (same); *Johnson & Johnson, Inc. v. Wallace A. Erickson & Co.*, 627 F.2d 57 (7th Cir. 1982) (reissue proceedings "have no effect whatever on the judicial process"); *PIC Inc. v. Prescon Corp.*, 495 F.Supp. 1302 (D. Del. 1980) (same; noting *ex parte*, non-adversarial nature of Patent Office reissue proceedings).

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[3] This requirement for disclosure of pending litigation is neither an idle nor insignificant obligation. In at least one reported instance, a reissue applicant's failure to comply with this litigation disclosure requirement contributed to a finding of inequitable conduct. *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997).

Thus, when the reissue proceeding is complete, the validity of the claims of the patent must be determined in this Court without deference to the Patent Office:

> The Courts are the final arbiter of patent validity and, although courts may take cognizance of, and benefit from, the proceedings before the patent examiner, the question is ultimately for the courts to decide, without deference to the ruling of the patent examiner.

Quad Environmental Tech v. Union Sanitary Dist., 946 F.2d 870, 876 (Fed. Cir. 1991).

Irrespective of whether Vysis retains the existing, "partially inoperative" claims of the '338 patent or obtains new claims, this Court will still need to evaluate Gen-Probe's claims of non-infringement and invalidity. Additionally, the reissue proceedings cannot dispose of Gen-Probe's claim for unfair competition arising out of Vysis bad-faith enforcement of the '338 patent, which it now admits is "partially inoperative." Nor can the reissue proceedings resolve the claim that the patent is unenforceable because Vysis engaged in inequitable conduct while prosecuting the '338 patent. *See* MPEP 1448; *e.g. Enprotech Corp. v. Autotech Corp.*, 15 U.S.P.Q. 2d 1319 (N.D. Ill. 1990). Nor can the Patent Office consider Gen-Probe's claim of unfair competition. Simply put, reissue will not dispose of this litigation.

C. Gen-Probe will suffer prejudice from the imposition of a stay.

Delay in resolving the issues raised by the First Amended Complaint will prejudice Gen-Probe and benefit Vysis. The Court need not search for a hidden motive behind Vysis pursuit of reissue proceedings and its failure to expedite the reissue proceedings as set forth above. That motive for delay arises from Gen-Probe's representations to the Court and Vysis that, in light of Vysis express and implied threats, it currently intends to continue to pay royalties on the '338 patent during the pendency of this suit. Thus, delay in the ultimate resolution of the reissue and this case works to Vysis' benefit. Indeed, if the reissue proceeding or this action results in a finding that the entirety of the claims of the '338 patent are invalid, Vysis could receive the benefit of millions of dollars of additional royalty payments simply as a result of the delay caused by the reissue application.

The prejudice to Gen-Probe from delay is particularly disturbing given Vysis' precarious financial status. According to Vysis' public reports, it has not yet generated any profits from its

business and is not even projected to do so until fourth quarter 2000 at best. (Vysis' Press Releases, NOL., Exhs. 3, 4.) Vysis' financial straits, coupled with its effort to create needless delay, create a grave concern that the stay will affect Gen-Probe's substantive rights in this case.

For example, should Gen-Probe succeed in its claim for unfair competition arising out of Vysis' bad-faith enforcement of the '338 patent, Gen-Probe will be entitled to recoup any royalty payments it pays during the pendency of this action. *See* Cal. Bus. & Prof. Code Section 17203.[4] However, if, at the delayed conclusion of this case, Vysis is financially unable to make restitution, Gen-Probe's remedy will be hollow. Accordingly, should the Court accept Vysis' motion to delay this case, fairness dictates that the Court impose suitable safeguards to ensure that Vysis does not use the resulting delay to collect extra royalty payments on an invalid patent.

D. The benefits of a stay are limited.

The only real benefit from a stay pending completion of the reissue process is that such a stay would permit the claims of the '338 patent to be finally and permanently fixed before the patent is submitted to scrutiny in this Court. A stay could admittedly preclude two rounds of judicial review of the patent. For this reason - and despite the inevitable delay in reaching the merits -- some courts have felt constrained to stay litigation in light of the possibility that patent claims might be modified in reissue proceedings, particularly where the patentee files the reissue application in the early stages of litigation.

E. The Court should impose reasonable conditions if a stay is granted.

Courts that have granted stays in the circumstances similar to those presented here have also routinely imposed conditions in connection with the stay in order to minimize the prejudice sustained by the other party from the resulting delay in final resolution of the issues. *E.g. United Merchants and Manufacturers, Inc. v. Henderson*, 495 F. Supp. 444 (N.D. Ga. 1980). Because Gen-Probe will suffer undue prejudice and competitive injury if the Court stays this case, Gen-Probe respectfully requests that the Court carefully craft appropriate conditions for the stay to minimize the resulting prejudice to Gen-Probe. Any stay imposed by this Court should be a

[4] All California Authorities are attached as exhibits to the concurrently filed Notice of Lodgment.

complete stay and should impose proper conditions in order to protect the processes of the Court and minimize prejudice to Gen-Probe. Moreover, the conditions should encourage Vysis to expedite its prosecution of the reissue application.

Gen-Probe requests that if the Court grants Vysis' motion, the Court also impose the following conditions:

- **Vysis should promptly advise the Patent Office of the pendency of this litigation and petition for special litigation processing of the reissue application**, as required by the Manual of Patent Examination Procedure § 1442.04;
- **Vysis should agree to forego any continuation practice** (or, alternatively, should Vysis desire or attempt to pursue any continuation of the pending reissue proceeding, the Court should promptly vacate the stay) (*Cf. United Sweetener*, 766 F.Supp. at 218-219 (stay would automatically lift at pre-determined point of Patent Office proceedings to prevent the use of appeals solely to delay the case);
- **Vysis should report in writing to the Court and Gen-Probe on 60-day intervals concerning the status of the reissue proceedings** (*ASCII Corp. v. STD Entertainment, Inc.*, 844 F.Supp. 1378 (N.D. Cal. 1994); *Dennco, Inc. v. Cirone*, 1995 US Dist. Lexis 9988 (D.N.H. 1995).);
- **Vysis should notify the Court and Gen-Probe within ten days when the Patent Office issues its final office action on the initial reissue application;**
- **The parties should establish an escrow account into which Gen-Probe shall pay all royalties due to Vysis under the terms of the license agreement pending the outcome of this action.** (This condition serves the dual purpose of providing the most likely *motivation* for Vysis to expedite the reissue proceedings and the only *secure* protection to ensure and secure Gen-Probe's entitlement to the return of its royalty payments at the conclusion of this case.[5])

[5] As is explained above, an order granting a stay will subject Gen-Probe to unreasonable and unnecessary financial risk. Where, as here, one of the parties is in a state of financial distress, the courts have not been reluctant to condition an order granting a stay on measures to reduce the financial risk to the party opposing the stay. *E.g., Apex Hosiery Co. v. Knitting Machines Corp.*, 90 F. Supp 763, 767 (D. Del. 1950) (stay conditioned on waiver of right to recover damages that

IV. THE COURT SHOULD REJECT VYSIS' REQUEST FOR ONE-SIDED DISCOVERY.

As part of its motion to stay the case, Vysis asks that the stay be one-sided: Vysis wants to obtain discovery from Gen-Probe to aid it in presenting its position to the Patent Office in the *ex parte* reissue proceedings. Among other things, Vysis seeks to obtain discovery of Gen-Probe's NAT kits such that it can further shape any reissue claims to encompass those products.

In considering Vysis' motion, it is important to consider that the reissue proceeding in the Patent Office is a one-sided, *ex parte* proceeding, in which Gen-Probe cannot participate in any meaningful way. While Gen-Probe has the right to file a single initial "protest" brief with the Patent Office within the first 60 days following the formal announcement of the reissue proceeding, Gen-Probe is absolutely precluded by regulation from any further participation in the reissue proceedings. 37 C.F.R. § 291(c); *Henkel Corp. v. Coral, Inc.*, 754 F.Supp. 1280, 1298 (N.D. Ill. 1990) ("The Patent Office eliminated the opportunity to fully participate as a protester, beyond the submission of an initial written protest, in 1982"); *In re Blaese*, 19 USPQ 2d 1232 (Comm'r. Pat. 1991) (the 1982 amendment to Rule 291 was specifically designed to ensure that the proceedings are essentially *ex parte*). Gen-Probe cannot reply to Vysis' response to Gen-Probe's protest, cannot respond in any way to other arguments made by Vysis in writing to the Patent Office, cannot comment on interim Patent Office rulings ("office actions"), cannot respond to Vysis' further amendments of the patent claims (if any), cannot attend the usual informal hearings or "interviews" conducted by the patent examiner to address issues which arise in the proceeding, and cannot participate in any appeal to Board of Patent and Trademark Appeals. *Id.*

Vysis' reissue application, and its motion to stay this action, clearly suggest that Vysis intends to try and take advantage of the *ex parte* nature of the reissue proceeding in the Patent Office and, if it is successful there, return to this Court and argue that the court must defer to the Patent Office's decision to issue amended claims. Vysis seeks to keep this case alive solely to

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would accrue while stay pending); *Bethlehem Steel Corp. v. Tishman Realty & Construction Co, Inc.*, 72 F.R.D. 33 (S.D.N.Y. 1976) (stay conditioned on the posting of a bond); *In re Hayes Microcomputer Products, Inc. Patent Litig.*, 982 F.2d 1527 (Fed. Cir. 1992) (percentage of sales placed in escrow account while injunction stayed during appeal).

permit Vysis to obtain unilateral discovery from Gen-Probe. Vysis seeks to obtain such discovery, which is not available in Patent Office reissue proceedings, in order to bolster its position in the *ex parte* reissue proceeding. At the same time it simultaneously seeks discovery and a stay here, Vysis also seeks to deny Gen-Probe any right to obtain discovery on the issues from Vysis.[6] If this case is to be stayed, it should be stayed. If discovery is to proceed, then it should proceed for both parties, not just one.

For example, Vysis claims that Gen-Probe's answers to discovery are "necessary for the Court and the parties to gain the full benefit of the reissue proceedings." (*Cf.*, Vysis Memorandum, at p. 8.) Yet, an identical argument may be made for the discovery that Gen-Probe served upon Vysis. That discovery was *also* timely served and, but for the parties' agreement to stay *all* discovery, would already have been answered. Among other things, that discovery seeks Vysis' explanations regarding its claims that Gen-Probe's NAT products infringe the '338 patent, Vysis' proposed construction of the claims of the '338 patent and an identification of all prior art of which Vysis is aware.[7] Certainly, to the extent that Gen-Probe's responses may be "necessary" for the Court and the parties, Vysis' responses may provide an even better standard by which the Court may ultimately assess the validity and propriety of Vysis' conduct in the reissue proceedings.

It would be manifestly unfair to permit Vysis to obtain one-sided discovery through this case, which would be otherwise stayed, in aid of Vysis' *ex parte* proceeding in the Patent Office.

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[6] Among the various facets of unfairness inherent in Vysis proposed unilateral discovery stay is the fact that the proposal would impose significant discovery costs on Gen-Probe. Yet, Vysis would avoid, or at a minimum defer, its own discovery costs for a significant amount of time. Moreover, to the extent that Vysis' motivation for the unilateral discovery stay is to aid the reissue proceeding, Gen-Probe has submitted corresponding discovery requests to Vysis that will go far to ensure Vysis' prompt and orderly disclosure of all prior art and related disclosures during the reissue. (*See* Gen-Probe's Discovery, NOL, Exhs. 5, 6.) The information sought by these requests will assist Gen-Probe in preparing its protest papers because it will (1) identify all of the material prior art possessed by Vysis, and (2) ensure that Gen-Probe (and the Patent Office) is aware of the scope of the claims asserted by Vysis. Both of these aspects are important to ensure that the Patent Office will be appraised of all the issues and art raised by Vysis' reissue.

[7] Gen-Probe has also sought discovery of relevant documents from various third parties affiliated with Vysis in the prosecution of the '338 patent. (Maloney Decl., ¶ 7.) Gen-Probe has agreed to stay the responses to that discovery pending the outcome of the Court's ruling of the motion to stay. (*Id.*, ¶ 9.)

The Court should either stay this case in its entirety or allow the parties to conduct bilateral discovery.

V. THE COURT SHOULD DENY VYSIS' ALTERNATIVE MOTION TO DISMISS THE UNFAIR COMPETITION CLAIM FOR RELIEF.

As an alternative to its motion to stay,[8] Vysis moves this Court to dismiss Gen-Probe's claim of unfair competition on the grounds that, according to Vysis, it has merely executed a license agreement and thus, according to its argument, has done nothing to "enforce" the '338 patent. Through that argument, Vysis relies upon specious reasoning and ignores the fundamental nature of the exclusionary rights inherent in the continued possession and assertion of a United States Patent. Vysis also ignores the accepted facts of the invalidity of the '338 patent and Vysis' express and implicit threats to enforce the '338 patent through litigation which induced the license agreement in the first instance. That argument also ignores significant Federal Circuit precedent that has recognized Gen-Probe's unfair competition claim.

To begin with, it is impossible to ignore the exceptionally high procedural burden that Rule 12(b)(6) imposes upon Vysis' effort to dismiss the fourth count. The Ninth Circuit has repeatedly cautioned that dismissal under Rule 12(b)(6) is proper only in extraordinary circumstances. *See, e.g., United States v. City of Redwood City*, 640 F.2d 963, 966 (9th Cir. 1981). District Courts may not dismiss claims under Rule 12(b)(6) "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of [its] claim that would entitle [it] to relief." *Schneider v. California Department of Corrections*, 151 F.3d 1194, 1196 (9th Cir. 1998). Furthermore, as noted above, this Court must accept as true the facts that Gen-Probe asserts in its complaint. *E.g., Cooper v. Pickett*, 137 F.3d at 623.

Accordingly, the Court must consider Vysis' motion in the context of several dispositive facts. First, the claims of the '338 patent are invalid in all material respects and the patent is unenforceable. (First Amended Complaint, ¶¶ 22, 30.) Furthermore, to the extent that a court would, or could, narrowly construe any of the claims of the '338 patent in a fashion to maintain

[8] The inclusion of the alternative motion within the motion to stay papers is contrary to Local Rule 7.1, which requires each motion to be separately stated and separately supported.

any semblance of validity, such construction would *not* encompass any of Gen-Probe's products. (*Id.*, ¶ 22.)

In addition, Vysis *knows* that the '338 patent is invalid and unenforceable. *Id.*, at ¶ 35. Despite that knowledge and in bad faith, Vysis has continued to enforce the '338 patent. *Id.* Based upon the facts alleged in the complaint, the Court must deny Vysis' alternative motion to dismiss the fourth count for unfair competition.

Gen-Probe's claim for unfair competition presents a cognizable claim arising from Vysis' previous and continuing acts of unfair competition. Thus, the Court must deny Vysis' alternative motion to dismiss Gen-Probe's fourth claim for relief.

For example, Gen-Probe alleges that Vysis' conduct violates Section 17200 of the California Business and Profession Code. This statute proscribes any unlawful, unfair or fraudulent business practice or conduct. *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal.4th 163, 180 (1999). This multi-faceted claim encompasses fraudulent practices that are likely to deceive members of the public. *See Saunders v. Superior Court*, 27 Cal.App.4th 832, 839 (1994). Thus, unlike common law fraud, a plaintiff may establish a Section 17200 violation even if no one was actually deceived, relied upon the fraudulent practice, or sustained any damage. *E.g.*, *Bank of the West v. Superior Court*, 2 Cal. 4th 1254, 1267 (1992).

As a further prong of Section 17200, the California courts have construed an "unlawful business practice" as any violation of law whether civil or criminal, federal, state or municipal, statutory, regulatory, or court-made. *E.g.*, *Stevens v. Superior Court*, 75 Cal.App.4th 594, 606 (1999). Finally, an unfair business practice, at least between competitors, includes any acts or practices that "threatens an incipient violation of the antitrust law, or violates the policy or spirit of one of those laws because its effects are comparable to or the same as a violation of the law, or otherwise significantly threatens or harms competition." *Cel-Tech*, 20 Cal.4th at 187.

The accepted facts and inferences attendant with Gen-Probe's fourth count make clear that Vysis' acts of bad-faith enforcement of an invalid patent constitute unlawful, unfair or fraudulent business practices or conducts in violation of Section 17200.[9]

[9] Technically, the first inquiry under Section 17200 is whether another law bars the unfair

Accordingly, at this procedural juncture, the statutory presumption of validity arising from 35 U.S.C. 282 is a smoke screen raised by Vysis to blur the Court's vision. Rather, the Court must accept the fact of invalidity and unenforceability - coupled with Vysis actual knowledge of those defects. The Court must also assume that Vysis knows that Gen-Probe's NAT products do not infringe any valid claim of the '338 patent. (*Id.*, ¶ 22.)

Accordingly, at this procedural juncture, Vysis cannot hide behind the statutory presumption of validity arising from 35 U.S.C. 282[10]. Rather, the Court must accept that the fact of invalidity and unenforceability - coupled with Vysis actual knowledge of those defects. The Court must also assume that Vysis knows that Gen-Probe's NAT products do not infringe any valid claim of the '338 patent. (*Id.*, ¶ 22.)

Vysis' argument that it has *merely* entered into a license agreement and thus has not "enforced" the invalid patent claims ignores reality and the further allegations of Gen-Probe's complaint. For example, soon after the '338 patent issued, Vysis first implemented its enforcement efforts for the '338 patent by contending that the '338 patent applied to Gen-Probe's NAT products. (*Id.*, ¶ 20). Particularly given the litigious nature of Vysis and its predecessor–in–interest, Amoco Technology Corporation, (*see id.*, ¶ 25), that "suggestion" provided a clear warning to Gen–Probe that Vysis would sue for infringement should Gen-Probe fail to acquiesce to Vysis' demand for royalty payments under a license agreement. (*See Id.*, ¶¶ 20, 25.) That evidence fully satisfies the requisite showing of unlawful and fraudulent conduct. In addition, given the statutory monopoly that accompanies the grant of a United States Patent, coupled with

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competition action. *Cel-Tech*, 20 Cal.4th at 184. Vysis has not challenged this issue - and for good reason. No state law bars this claim and, in a series of decisions, the Federal Circuit has established that federal patent law does *not* preempt state law claims for unfair competition that depend upon facts of bad-faith enforcement of invalid patents. *E.g., Zenith Electronics Corp. v. Exzec Inc.*, 182 F.3d 1340, 1355 (Fed. Cir. 1999).

[10] The presumption of patent validity is purely a *procedural* device. It simply assigns to the party that asserts that a patent is invalid the burden of proving invalidity. *Avia Group International, Inc. v. L.A. Gear California*, 853 F.2d 1557, 1562 (Fed. Cir. 1988); *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). The presumption does not have any substantive evidentiary significance. *New England Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992) (presumption insufficient to establish probability of success on the merits in context of injunctive relief); *Nutrition 21 v. United States*, 930 F.2d 862, 869 (Fed. Cir. 1991) (same).

Vysis' knowledge that the claims of the '338 patent were invalid and did *not* apply to Gen-Probe's products, that prior conduct of Vysis establishes the alternative prong of unfairness. *See, e.g., Argus Chemical Corp. v. Fibre Glass-Evercoat Co.* 812 F.2d 1381, 1386 (Fed. Cir. 1987).

Furthermore, even disregarding the early evidence of Vysis' unlawful, unfair or fraudulent business practices and conduct, Gen-Probe has also alleged Vysis' *continuing activities* by which it has continued to enforce the '338 patent notwithstanding actual knowledge of the invalidity, unenforceability and non-infringement of the '338 patent. Specifically, to eliminate any doubt concerning Vysis' knowledge that the claims of the '338 patent are invalid and that Gen-Probe's products do not infringe, Gen-Probe alleged the facts substantiating its recent disclosure to Vysis of prior art references that invalidate the claims of the '338 patent. (First Amended Complaint, ¶ 23.) In the face of that further disclosure and notwithstanding Vysis' actual knowledge of the invalidity and unenforceability of the '338 patent, Vysis has persisted in its public denial and has continued to insist that the '338 patent is valid and that Gen-Probe's NAT products infringe that patent. (*Id.*, ¶ 24.) This conduct alone satisfies the fraudulent prong of Section 17200.[11]

Moreover, the argument that Gen-Probe's remedy for Vysis' fraudulent enforcement of a knowingly invalid patent is merely to cease royalty payments ignores the fact, as alleged, that Gen Probe's failure to render royalty payments will result in Vysis' aggressive efforts to terminate the license agreement and initiate infringement suits against Gen-Probe and its allied collaborators and customers. (First Amended Complaint, ¶ 25.) That continuing threat of aggressive litigation provides still further evidence of the enforcement muscle that Vysis wields through the '338 patent and the license agreement.

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[11] As indicated above, Gen-Probe has shown an adequate basis for its unfair competition claim and further shown that the claim does not depend upon Vysis supposition of a claim for "wrongful" or malicious defense. (Vysis' Memorandum, at p. 10-11.) Nonetheless, Gen-Probe notes that Vysis' proposition that it cannot be guilty of unlawful, unfair or fraudulent business practices, as a matter of law, for "merely" enforcing a patent license agreement prior to *compelling* a judicial determination of invalidity presents a troubling argument. Gen-Probe suggests that an independent claim for unfair competition and anti-competitive activity will arise should Gen-Probe ultimately prevail and prove that, notwithstanding Vysis' *actual knowledge* of invalidity, it nonetheless judicially denied such knowledge and *forced* a judicial finding of invalidity in order to continue to collect royalties on an invalid patent pursuant to its license agreement.

Finally, Vysis' fraudulent conduct in violation of Section 17200 is virtually established through the pleadings coupled with Vysis' response to Gen-Probe's disclosure of invalidating prior art. (*See Id.*, ¶¶ 23-24.) As the extrinsic evidence proffered by Vysis discloses, Vysis initially responded to Gen-Probe's proffer by denying *any* infirmity in the '338 patent. (*See* Galloway letter dated January 19, 2000, Vysis Exh. C.) Yet, notwithstanding this response, Vysis then initiated reissue proceedings in an attempt to "cure" the invalidating defects that Gen-Probe brought to Vysis' attention. Vysis' reissue declaration at least tacitly evidences its concern that the broad claims of the '338 patent are invalid in light of the prior art that Gen-Probe submitted. That tacit concern raises a strong inference of a violation of section 17200 when viewed in the context of Vysis' January 13, 2000 response to Gen-Probe.

Thus, the Court must deny Vysis' alternative motion to dismiss Gen-Probe's fourth count for Unfair Competition. Given the facts of Vysis' knowledge of the invalidity, non-infringement and unenforceability of the '338 patent, Vysis cannot show beyond doubt that Gen-Probe can prove no set of facts in support of its claim that would entitle it to relief. *See, e.g., Schneider v. California Department of Corrections*, 151 F.3d 1194, 1196 (9th Cir. 1998).

As a corollary to the *present* viability of Gen-Probe's claim for unfair competition, that claim will remain viable notwithstanding the outcome of Vysis' resort to reissue proceedings. Thus, to the extent that Vysis purports to buttress its motion for a stay upon express or implied suggestions that the reissue proceeding can dispose of the entire case, that argument is simply wrong and misrepresents the limited nature of reissue proceedings.

First, there are a discrete number of outcomes of the reissue proceeding. None of those outcomes will obviate this litigation and, in particular, Gen-Probe's claim for unfair competition. For example, irrespective of the Patent Office's decision on reissue, this Court retains jurisdiction to review any reissue patent, to determine the validity of the reissue claims, and to evaluate Vysis' past and future conduct before the Patent Office and in enforcing the invalid '338 patent. Because this Court is *not* bound by any determination of the Patent Office, (*e.g., Yates-American Machine Co., Inc. v. Newman Machine Co., Inc.*, 694 F. Supp. 155, 158 (M.D.N.C. 1988).), Gen-Probe's unfair competition claim will remain viable even under the best of reissue outcomes for Vysis.

Second, reissue proceedings cannot adjudicate or resolve acts of inequitable conduct committed in the prosecution of the original patent. *E.g.* MPEP 1448 ("The Office no longer investigates and rejects reissue applications under 37 CFR 1.56. The Office will not comment upon any duty of disclosure issues which are brought to the attention of the Office in reissue applications . . . ."); *see also, Enprotech Corp.*, 15 U.S.P.Q. 2d 1319. Based upon the limited evidence available to date, and particularly when viewed in the context of the tortured prosecution of the '338 patent, Gen-Probe believes that the issue of inequitable conduct and resulting unenforceability will remain for resolution. Even assuming, *arguendo*, that the Patent Office and this Court determine that *all* of the original and reissue claims, if any, are valid, Gen-Probe's unfair competition claim will remain viable to the extent that Vysis has enforced -- and continues to enforce -- a patent that is unenforceable due to the inequitable conduct committed by it or its predecessor in interest.

VI. CONCLUSION.

As set forth above, a stay will not ultimately eliminate or dispose of Gen-Probe's claims. Nonetheless, should the Court impose a stay, the Court should impose suitable conditions to minimize the prejudice that Gen-Probe will sustain from the delay that will result from Vysis' reissue proceedings.

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If a stay is granted but Vysis fails to prosecute the reissue application with utmost diligence, Gen-Probe reserves the right to move to vacate the stay. *United Merchants & Mfrs., Inc. v. Henderson,* 495 F. Supp. 444, 447 (N.D. Ga. 1980); *Reiter v. Universal Marion Corporation,* 173 F. Supp. 13, 17 (D. D.C. 1959).

Dated: April 10, 2000

COOLEY GODWARD LLP
STEPHEN P. SWINTON (106398)
JAMES J. DONATO (146140)
PATRICK M. MALONEY (197844)

GEN-PROBE INCORPORATED
R. WILLIAM BOWEN, JR. (102178)

By: Patrick M. Maloney
Patrick M. Maloney

Attorneys for Plaintiff,
GEN-PROBE INCORPORATED

PROOF OF SERVICE (FEDERAL EXPRESS)

I, Lindsay Dillow, hereby declare:

I am employed in the City of San Diego, County of San Diego, California in the office of a member of the bar of the court in which the within action is pending at whose direction the following service was made. I am over the age of eighteen years and not a party to the within action. My business address is Cooley Godward LLP, 4365 Executive Drive, Suite 1100, San Diego, California 92121-2128. I am personally and readily familiar with the business practice of Cooley Godward LLP for collection and processing of notices and other papers to be sent by overnight delivery service by Federal Express. Pursuant to that business practice, envelopes and packages are placed for collection at designated stations and in the ordinary course of business are that same day deposited in a box or other facility regularly maintained by such express service carrier or delivered to an authorized courier or driver authorized by such express service carrier to receive documents, in an envelope or package designated by such express service carrier, with delivery fees paid or provided for.

On April 10, 2000, I served: **NOTICE OF LODGMENT IN SUPPORT OF GEN-PROBE INCORPORATED'S RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B) (6), DECLARATION OF PATRICK M. MALONEY IN SUPPORT OF GEN-PROBE INCORPORATED'S RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B) (6) AND MEMORANDUM OF POINTS AND AUTHORITIES OF GEN-PROBE INCORPORATED IN RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6)** on the interested parties in this action by placing a true copy thereof, on the above date, enclosed in a sealed envelope, at a station designated for collection and processing of envelopes and packages for overnight delivery service by Federal Express as part of the ordinary business practice of Cooley Godward LLP described above, addressed as follows:

PROOF OF PERSONAL SERVICE

I, ANDREW HARRISON, hereby declare:

I am employed in the City of San Diego, County of San Diego, California; I am over the age of eighteen years and not a party to the within action; my business address is Advanced Attorney Service, 1785 Hancock Street, Suite 200, San Diego, CA 92110.

On April 10, 2000, I served the within: **NOTICE OF LODGMENT IN SUPPORT OF GEN-PROBE INCORPORATED'S RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B) (6), DECLARATION OF PATRICK M. MALONEY IN SUPPORT OF GEN-PROBE INCORPORATED'S RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B) (6) AND MEMORANDUM OF POINTS AND AUTHORITIES OF GEN-PROBE INCORPORATED IN RESPONSE TO VYSIS' MOTION: (1) FOR A STAY OF PROCEEDINGS AND, ALTERNATIVELY, (2) TO DISMISS COUNT FOUR UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6)** on the interested parties in this action by personally hand delivering a copy of said document(s) to the address(es) listed below:

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Wright and L'Estrange
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Attorneys for Vysis, Inc.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on April 10, 2000.

(signature)

ANDREW HARRISON
(print name)

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on April 10, 2000, at San Diego, California.

Lindsay Dillow

EXHIBIT 4

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED, Plaintiff, v. VYSIS, INC., Defendant.	No. 99cv2668 H (AJB) **GEN-PROBE INCORPORATED'S OBJECTIONS AND RESPONSES TO VYSIS, INC.'S SECOND SET OF INTERROGATORIES**

PROPOUNDING PARTY: **DEFENDANT VYSIS, INC.**

RESPONDING PARTY: **PLAINTIFF GEN-PROBE INCORPORATED**

SET NUMBER: **TWO (2)**

Pursuant to Federal Rule of Civil Procedure 33, Plaintiff Gen-Probe Incorporated ("Gen-Probe") responds as follows to Defendant Vysis, Inc.'s ("defendant") second set of interrogatories:

I. GENERAL RESPONSES.

1. Gen-Probe's response to defendant's second set of interrogatories is made to the best of Gen-Probe's present knowledge, information, and belief. Said response is at all times subject to such additional or different information that discovery or further investigation may disclose and,

while based on the present state of Gen-Probe's recollection, is subject to such refreshing of recollection, and such additional knowledge of facts, as may result from Gen-Probe's further discovery or investigation. Gen-Probe reserves the right to make any use of, or to introduce at any hearing and at trial, information and/or documents responsive to defendant's first set of interrogatories but discovered subsequent to the date of this response, including, but not limited to, any such information or documents obtained in discovery herein.

2. To the extent that Gen-Probe responds to defendant's interrogatories by stating that Gen-Probe will provide information and/or documents which Gen-Probe, any other party to this litigation, or any other person or entity deems to embody material that is private, business confidential, proprietary, trade secret, or otherwise protected from disclosure pursuant to Federal Rule of Civil Procedure 26(c)(7), Federal Rule of Evidence 501, California Evidence Code section 1060, or California Constitution, article I, section 1, or any like or similar provision of law of any jurisdiction Gen-Probe will do so only upon the entry of an appropriate protective order against the unauthorized use or disclosure of such information.

3. Gen-Probe reserves all objections or other questions as to the competency, relevance, materiality, privilege or admissibility as evidence in any subsequent proceeding in or trial of this or any other action for any purpose whatsoever of Gen-Probe's responses herein and any document or thing identified or provided in response to defendant's interrogatories.

4. Gen-Probe reserves the right to object on any ground at any time to such other or supplemental interrogatories as defendant may at any time propound involving or relating to the subject matter of these interrogatories.

II. GENERAL OBJECTIONS.

1. Gen-Probe makes the following general objections, whether or not separately set forth in response to each interrogatory, to each instruction, definition, and interrogatory made in defendant's first set of interrogatories:

2. Gen-Probe objects generally to interrogatories 3 through 9, insofar as they seek information or production of documents protected by the attorney-client or the attorney work product privilege. Such information or documents shall not be provided in response to defendant's

interrogatories and any inadvertent disclosure or production thereof shall not be deemed a waiver of any privilege with respect to such information or documents or of any work product immunity, which may attach thereto.

3. Gen-Probe objects generally to each interrogatory to the extent it seeks to require Gen-Probe to identify in this response each or any document or other information which may relate to, reflect or otherwise refer to specified matters on the ground that such requests collectively encompass potentially thousands of pages of documents not all of which have or can be located and reviewed by counsel within the time period allowed by statute for this response. Accordingly, said request would subject Gen-Probe to unreasonable and undue annoyance, oppression, burden, and expense.

4. Gen-Probe objects to Definition B to the extent it defines "Gen-Probe" to include Gen-Probe's predecessors or successors; past or present divisions, subsidiaries, parents, or affiliates of any of the foregoing entities; past or present joint ventures, partnerships, or limited partnerships of which any of the foregoing entities is a joint venturer or a limited or general partner; and past or present directors, officers, employees, agents, or representatives of any of the foregoing entities. Said definition is vague and ambiguous in that it cannot be determined what is meant by the term "Gen-Probe." Said definition is also overly broad, seeks irrelevant information not calculated to lead to the discovery of admissible evidence, and would subject Gen-Probe and the other entities identified in the definition to unreasonable and undue annoyance, oppression, burden and expense.

5. Gen-Probe objects to Definition E to the extent that it defines the phrase "target capture" to the extent the definition provided is broader than any disclosure of the '338 patent.

6. Gen-Probe objects to the introductory statement to the extent it suggests that the interrogatories are continuing, on the ground that said instruction seeks unilaterally to impose an obligation to provide supplemental information greater than that required by Federal Rule of Civil Procedure 26(e) and would subject it to unreasonable and undue annoyance, oppression, burden, and expense. Gen-Probe will comply with the requirements of the Federal Rules of Civil Procedure and is willing to discuss mutually acceptable reciprocal obligations of defendant for continuing discovery.

COOLEY GODWARD LLP
ATTORNEYS AT LAW
SAN DIEGO

7. Gen-Probe objects to Definition B and Instruction A to the extent that they seek to require Gen-Probe to search for information, documents and information about documents no longer in existence or no longer in Gen-Probe's possession, custody or control, on the grounds that said instruction is overly broad, would subject Gen-Probe to undue annoyance, oppression, burden and expense, and seeks to impose upon Gen-Probe an obligation to investigate information or materials from third parties or services who are equally accessible to defendant.

8. Gen-Probe objects to Instruction A to the extent it seeks to require Gen-Probe to identify anything other than the specific claim or privilege or work product being made and the basis for such claim, on the ground that the additional information sought by defendant would subject Gen-Probe to unreasonable and undue annoyance, oppression, burden, and expense, and constitutes information protected from discovery by privilege and as work product.

III. SPECIFIC OBJECTIONS AND RESPONSES TO INTERROGATORIES.

Without waiving or limiting in any manner any of the foregoing General Objections, but rather incorporating them into each of the following responses to the extent applicable, Gen-Probe responds to the specific interrogatories in defendant's first set of interrogatories as follows:

INTERROGATORY NO. 3:

State in detail each and every legal and factual basis for, and identify all documents and/or all non-written communications that refer or relate in any manner to, Gen-Probe's allegation in paragraph 35 of its First Amended Complaint that "Vysis has acted and continues to act unfairly, inequitably and in bad faith" and that "Vysis' actions constitute unlawful, unfair or fraudulent business practices under California Business & Professions Code Sections 17200, *et. seq.*"

RESPONSE TO INTERROGATORY NO. 3:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects to this interrogatory to the extent that it prematurely seeks the facts and contentions that Gen-Probe will advance at trial before the completion of investigation and discovery. Without waiving, and subject to, the foregoing objections, Gen-Probe will agree to disclose the bases upon which it asserted the allegations of paragraph 35 of the First Amended Complaint and responds as follows:

Although Vysis knows or should know that the '338 patent is invalid, unenforceable and does not encompass methods or compositions used in Gen-Probe's products, Vysis in early 1999 took the position that Gen-Probe would be liable for patent infringement unless Gen-Probe took a license to the '338 patent. In early 1999, Vysis informed Gen-Probe that the '338 patent applied to Gen-Probe's nucleic acid tests for HIV and hepatitis for use in screening donated blood. Vysis continued to take this position in subsequent communications between the parties. Vysis's actions must be considered in light of the prior conduct of Vysis, its predecessors, and its affiliates toward Gen-Probe. Written communications include the letters from John Bishop of Vysis to Henry L. Nordhoff of Gen-Probe dated February 11, 1999 and February 17, 1999. Oral communications were made primarily between March 1999 and June 22, 1999 in connection with various discussions in San Diego between the parties.

In December 1999, through a letter from Peter Shearer, Gen-Probe informed Vysis of invalidating prior art. Vysis responded to Mr. Shearer's letter on January 19, 2000, professing satisfaction with the '338 patent. Notwithstanding the foregoing, Vysis continued to maintain that the patent is valid and that Gen-Probe is subject to the earlier executed license to the '338 patent.

INTERROGATORY NO. 4:

Identify by name, model number, or other designation, each current and past product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe NAT test kits for use in detecting HCV or HIV. For each product identified, indicate the dates during which manufacture and/or sales of the product occurred, the address locations at which manufacture and/or sales occurred, each person to whom the product was sold, any feature that is believed to distinguish the product from the claims of the '338 patent.

RESPONSE TO INTERROGATORY NO. 4:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this interrogatory is vague and ambiguous with respect to the term "amplification." Gen-Probe further objects to this interrogatory to the extent that it prematurely seeks the facts and contentions that Gen-Probe will

advance at trial before the completion of investigation and discovery. Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe responds as follows:

No Gen-Probe product uses "target capture" or "amplification" within the meaning of those terms as used in the properly construed claims of the '338 patent. Gen-Probe understands the term "product" as used in this interrogatory to mean a product that has been the subject of a commercial sale and understands the term "product" to exclude nucleic acid tests that have been transferred for use in connection with clinical trials. Subject to all of the foregoing, Gen-Probe responds that its nucleic acid tests for the detection of HIV and hepatitis C virus ("HCV") in donated blood and blood products use a form of target capture and a form of amplification that are not disclosed or claimed in the '338 patent. Between January 1, 1999 and March 30, 2000 Gen-Probe had sold kits for the detection of HIV and HCV (in 5,000-test kits and 1,000-test kits) to Chiron Corporation, Bayer Corporation, and Chugai Diagnostic Sciences Co., Ltd. These products were manufactured at 10210 Genetic Center Drive, San Diego, California and at 10808 Willow Court, San Diego, California. Gen-Probe believes that the HIV/HCV tests are not encompassed by the properly construed claims of the '338 patent for the reasons previously set forth in response to Interrogatory No. 2.

INTERROGATORY NO. 5:

Identify each opinion, report, study, or search results, written or oral, received by, requested by, or known to Gen-Probe relating to the validity, scope, or enforceability of one or more claims of the '338 patent or to the infringement or non-infringement of one or more claims of the '338 patent by any of the products identified in Interrogatory No. 4 including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO INTERROGATORY NO. 5:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe also objects that to the extent this

request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe declines to respond on the grounds of the attorney-client privilege and attorney work product.

INTERROGATORY NO. 6:

List separately and identify: licenses, agreements, contracts or undertakings, either foreign or domestic, entered into by Gen-Probe with third parties, including documents relating to any contemplated licenses, agreements, contracts or undertakings, either foreign or domestic, relating to each product identified in Interrogatory No. 4, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO INTERROGATORY NO. 6:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the interrogatory is overbroad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe responds as follows:

On June 11, 1998, Gen-Probe has entered into an agreement with Chiron Corporation relating to nucleic acid tests for use in blood screening and clinical diagnostics. Chiron subsequently assigned its rights in the clinical diagnostics portion of the agreement to Bayer Corporation

INTERROGATORY NO. 7:

State in detail each factual and each legal basis for Gen-Probe contention that the '338 patent is unenforceable, including each unenforceability contention advanced by Gen-Probe in briefing on Vysis' motion for a stay of these proceedings.

RESPONSE TO INTERROGATORY NO. 7:

Gen-Probe incorporates into this response each of the foregoing General Responses and

General Objections as if fully set forth herein. Gen-Probe also objects that to the extent this interrogatory seeks information relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the interrogatory is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects to this interrogatory to the extent that it prematurely seeks the facts and contentions that Gen-Probe will advance at trial before the completion of investigation and discovery. Without waiving, and subject to, the foregoing objections, Gen-Probe will agree to disclose the bases upon which it asserted in its briefing on Vysis' motion to stay that the '338 patent is unenforceable and responds as follows:

The '338 patent is unenforceable due to Vysis's inequitable conduct in the prosecution of its applications for the patent, as follows:

The patent applicant delayed the prosecution of the applications for the method invention from the filling of the 136,920 application on December 21, 1987 through at least the issuance of the patent on May 12, 1998, a period of 10 ½ years.

In connection with the petition to revive the abandoned 07/944,505 application, the patent applicant misrepresented to the PTO that the '505 application had been *unintentionally* abandoned.

The patent applicant failed to maintain consonance with the segregation of the method and device inventions after the filing of applications 944,505 and 648,468, by amending application no. 238,080 to allege that it was a divisional of application no. 400,657.

In the December 14, 1998 Request for Certificate of Correction, the patent applicant represented to the PTO that the mistakes identified in the Request were of minor character and resulted from errors made in good faith.

In the December 14, 1998 Request for Certificate of Correction, the patent applicant representing to the PTO that the mistakes identified in the Request were first identified after the issuance of the '338 patent and that the so-called "Error 2" had "only recently" been identified, when in fact Error 2 had been identified in 1995 and an amendment requested on March 8, 1995 in the course of the prosecution of application 08/400,657.

In the December 14, 1998 Request for Certificate of Correction, the patent applicant

represented to the PTO that the failure to respond to the November 5, 1992 Office Action concerning the '505 application had been inadvertent and that the '505 application had been unintentionally abandoned.

The patent applicant failed to maintain consonance with the segregation of the method and device inventions after the filing of applications 944,505 and 648,468, by changing the priority claim of the '338 patent to assert that the '080 application was a continuation of application no. 124,826.

In the December 14, 1998 Petitions Requesting Entry of Amendment To Abandoned Applications, the patent applicant represented to the PTO that *Sampson v. Commissioner*, 195 U.S.P.Q. 136 (D.D.C. 1976), supported the amendments sought in the Petitions.

The patent applicant filed the reissue application in March 2000 without advising the PTO of the prior post-issuance amendments and corrections to the '338 patent sought in December 1998 and entered thereafter.

The patent applicant failed to advise the PTO that the term "amplify" as used in the applications for the '338 patent (and the corresponding reissue application), properly construed, did not include target specific amplification.

INTERROGATORY NO. 8:

Identify all persons with knowledge of any of the facts listed in Gen-Probe's responses to Vysis' interrogatory Nos. 1-7.

RESPONSE TO INTERROGATORY NO. 8:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Without waiving, and subject to, the foregoing objections, Gen-Probe responds as follows:

Peter Shearer; Christine Gritzmacher; Dan Kacian; William Bowen; Henry L. Nordhoff; John Bishop; Norval Galloway, Anthony Janiuk; Charles E. Lipsey; Thomas Ryan; Hon. Ronald Prager; Thomas Banks; Mark Collins; Donald Halbert; Walter King; Jonathan Lawrie; Scott Decker; Sherrol McDonough; Martha Bott; Sharon Bodrug.

///

INTERROGATORY NO. 9:

State in detail each factual and each legal basis, other than non-infringement of the '338 patent by Gen-Probe's NAT test kits for detecting HCV or HIV, invalidity of the '338 patent, or unenforceability of the '338 patent, for the statement in paragraph 22 of Gen-Probe's First Amended Complaint for Declaratory Relief and Unfair Competition that "Gen-Probe contends that it has no obligation to make any royalty payments to Vysis with respect to its present products and activities and any contemplated products and activities," if Gen-Probe contends other bases exist.

RESPONSE TO INTERROGATORY NO. 9:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects to this interrogatory to the extent that it seeks prematurely, before the completion of investigation and discovery, the facts and contentions that Gen-Probe will advance at trial. Without waiving, and subject to, the foregoing objections, Gen-Probe will agree to disclose the bases upon which it asserted the allegations of paragraph 22 of the First Amended Complaint and responds as follows:

At this time, Gen-Probe does not contend that it has no obligation to make any royalty payments to Vysis with respect to its present products and activities and any contemplated products and activities on any basis other than invalidity, unenforceability, and the fact that Gen-Probe's products are not encompassed by the properly construed claims of the '338 patent.

Dated: June 20, 2000

COOLEY GODWARD LLP
STEPHEN P. SWINTON (106398)
JAMES DONATO (146140)
PATRICK M. MALONEY (197844)

GEN-PROBE INCORPORATED
R. WILLIAM BOWEN, JR. (102178)

By: _____
Stephen P. Swinton

Attorneys for Plaintiff
Gen-Probe Incorporated

EXHIBIT 5

cal SC

00 SEP 15 AM 8:57

CLERK DEPUT

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED, Plaintiff, v. VYSIS, INC., Defendants.	Civil No. 99cv2668 H(AJB) SCHEDULING ORDER

Pursuant to Rule 16.1 (d) (6) of the Local Rules, a Case Management Conference was held on September 13, 2000. After consulting with the attorneys of record for the parties and being advised of the status of the case, and good cause appearing,

IT IS HEREBY ORDERED:

1. On or before April 23, 2001, each party shall comply with the opening disclosure report provisions in Rule 26(a)(2)(A) and (B) of the Federal Rules of Civil Procedure. Any opposing reports shall be exchanged on or before May 18, 2001.

2. Any party shall supplement its disclosure regarding contradictory or rebuttal evidence under Rule 26(a)(2)(c)on or before May 29, 2001.

3. **Please be advised that failure to comply with this section or any other discovery order of the court may result in the sanctions provided for in Fed.R.Civ.P.37 including a prohibition on the introduction of experts or other designated matters in evidence.**

48[1]

4. All fact discovery shall be completed by all parties on or before April 17, 2001. All expert discovery shall be completed by all parties on or before June 15, 2001. "Completed" means that all discovery under Rules 30-36 of the Federal Rules of Civil Procedure, and discovery subpoenas under Rule 45, must be initiated a sufficient period of time in advance of the cut-off date, *so that it may be completed* by the cut-off date, taking into account the times for service, notice and response as set forth in the Federal Rules of Civil Procedure. **All discovery conferences must be calendared within 30 days of the dispute arising.**

5. All other pretrial motions must be filed so that they may be heard on or before August 6, 2001. Please be advised that counsel for the moving party must obtain a motion hearing date from the law clerk of the judge who will hear the motion. Be further advised that the period of time between the date you request a motion date and the hearing date may vary from one district judge to another. Please plan accordingly. For example, you should contact the judge's law clerk in advance of the motion cut-off to calendar the motion. Failure to make a timely request a motion date may result in the motion not being heard.

6. Counsel shall file their Memoranda of Contentions of Fact and Law and take any other action required by Local Rule 16.1 (f) (3) on or before September 10, 2001.

7. Counsel shall comply with the Pre-trial disclosure requirements of Federal Rule of Civil Procedure 26(a)(3) on or before September 10, 2001.

8. Counsel shall meet and take the action required by Local Rule 16.1 (f) (5) on or before September 24, 2001.

9. Objections to Pre-trial disclosures shall be filed no later than October 1, 2001.

10. The Proposed Final Pretrial Conference Order required by Local Rule 16.1 (f) (7) shall be prepared, served, and lodged on or before October 1, 2001.

11. The final Pretrial Conference is scheduled on the calendar of Judge Huff on ***October 8, 2001 at 10:30 a.m.***

12. A post trial settlement conference before a magistrate judge may be held within 30 days of verdict in the case.

13. The dates and times set forth herein will not be modified except for good cause shown.

14. Dates and times for hearings on motions should be approved by the Court's clerk before notice of hearing is served.

15 Briefs or memoranda in support of or in opposition to any pending motion shall not exceed twenty-five (25) pages in length without leave of a district court judge. No reply memorandum shall exceed ten (10) pages without leave of a district court judge. Briefs and memoranda exceeding ten (10) pages in length shall have a table of contents and a table of authorities cited.

IT IS SO ORDERED.

Dated: 9/14/00

ANTHONY J. BATTAGLIA
United States Magistrate Judge

cc: Judge Huff
All Counsel of Record

EXHIBIT 6

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER L.L.P.
CHARLES E. LIPSEY (*In Pro Hac Vice*)
EDNA VASSILOVSKI (*In Pro Hac Vice*)
THOMAS W. BANKS (195006)
JOHN W. BURNS (190031)
700 Hansen Way
Palo Alto, CA 94304
Telephone: (650) 849-6600
Facsimile: (650) 849-6666

WRIGHT & L'ESTRANGE
JOHN H. L'ESTRANGE, JR. (49594)
JOSEPH T. ERGOSTOLO (137807)
701 B Street, Suite 1550
San Diego, CA 92101
Telephone: (619) 231-4844
Facsimile: (619) 231-6710

Attorneys for Defendant VYSIS, INC.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. 99CV2668 H (AJB)

DECLARATION OF NORVAL B. GALLOWAY

Date: September 15, 2000
Time: 9:30 a.m.
Dept.: Courtroom A

I, Norval B. Galloway, declare:

1. I am Patent Counsel for Vysis, Inc., the defendant in the present litigation between Gen-Probe Incorporated (Gen-Probe) and Vysis, Inc. (Vysis).

2. Vysis is a small company with limited financial resources. Vysis employs only two in-house lawyers, its general counsel and me. I am Vysis's in-house patent attorney and the only attorney at Vysis with detailed familiarity with the patent-in-suit, U. S. Patent No. 5,750,338 (the '338 patent), its history, and the technical subject matter and issues involved in this suit. I am also the only attorney at Vysis with detailed familiarity with the '338 patent reissue application now before the Patent Office. There is no one else at Vysis who can knowledgeably and efficiently

interact with Vysis's outside counsel in these two proceedings involving the '338 patent. I believe my participation in both proceedings involving the '338 patent is critical to protecting the interests of Vysis and instructing outside counsel in those cases.

3. Vysis and Gen-Probe, parties in the present suit, were previously both parties in Case No. 95-CV-998-J (BTM), a patent infringement suit also filed in the Southern District of California. That case was filed by Gen-Probe alleging that the activities of Vysis in a number of areas, including assays for infectious diseases, infringed Gen-Probe's patents. The parties stipulated to a protective order in the case that specifically allowed both Vysis and Gen-Probe to designate an in-house attorney and two officers, directors or employees with free access to all of the opposing parties' confidential information. All attorneys of record also had full access to confidential information produced in discovery. Gen-Probe did not try to restrict access to confidential information by any of Vysis's in-house counsel or its corporate officers, or impose any restriction on patent prosecution activity. A copy of that protective order is attached as Exhibit A. Gen-Probe has not accused Vysis of violating the previous protective order or of misusing Gen-Probe's confidential information from that case.

4. The previous case settled on August 10, 1999. The terms of the settlement effectively prohibit Vysis from competing with Gen-Probe in the field of infectious disease testing. The terms prohibit Vysis from using tests it developed to compete with Gen-Probe for the detection of infectious diseases. Vysis has never competed in the blood screening field in which the Gen-Probe NAT test kit products that are the subject of this action compete.

5. As an additional condition of settling the previous patent infringement lawsuit, Gen-Probe insisted upon a license under Vysis's '338 patent, one of the Collins patents, the patent-in-suit. Three letters between the parties discussing the settlement, two dated March 29, 1999 and one dated April 9, 1999, are attached to this declaration as Exhibits B, C and D.

6. On December 22, 1999, just three and one-half months after the previous suit was settled, Gen-Probe filed this new lawsuit against Vysis, asking for declaratory judgment that the '338 patent is invalid or not infringed, and to excuse Gen-Probe from paying royalties due under the license.

7. On March 8, 2000, Vysis filed a patent reissue application with the PTO for the '338 patent based on a belief that the patent is partially inoperative for failure to assert claims of intermediate scope. The new claims that Vysis proposes to add to the patent through the reissue process are narrower than the broadest claims in the original patent and do not cover subject matter outside that already encompassed by the original patent claims. The reissue proceeding is being conducted on the public record to which the public has full access. Gen-Probe has been provided with a copy of the reissue application. I understand Gen-Probe has filed a protest to the application with the PTO.

8. Vysis is represented in this litigation by outside counsel, Finnegan, Henderson, Farabow, Garrett & Dunner (Finnegan Henderson) and specifically by Charles E. Lipsey. It has retained Wright & L'Estrange as local counsel to assist Finnegan Henderson with local procedures. Mr. Lipsey has substantial familiarity with the '338 patent and the relevant technology. His participation in both this litigation and the patent reissue proceeding are essential for protecting Vysis's legal interests. Neither Finnegan Henderson, Wright & L'Estrange, nor any of their attorneys or staff do any patent prosecution for Vysis other than the application to reissue the '338 patent.

9. Apart from the reissue application, Finnegan Henderson does not represent Vysis in patent prosecution matters. Finnegan Henderson has no general familiarity with Vysis' portfolio of intellectual property and provides no regular advice to Vysis with respect to Vysis' research, development, and business activities. To the contrary, Vysis regularly is represented by a number of firms other than Finnegan Henderson for patent prosecution and business matters. Finnegan Henderson's representation of Vysis is limited to adversarial matters such as this litigation and issues relating to them. Finnegan Henderson has previously represented Vysis in matters involving Gen-Probe, including the prior litigation identified in paragraph 3 above. Finnegan Henderson became familiar with the '338 patent and the history of this case as a result of that prior representation. Thus, I believe it is essential for Vysis that Finnegan Henderson represents Vysis with respect to the reissue application as well as this lawsuit.

10. Gen-Probe's current HIV and HCV kits licensed under the '338 patent are widely distributed to blood screening institutions. These kits are distributed with a package insert detailing the operation of the test. To date, Gen-Probe has refused to produce documents or permit discovery with respect to future products. Attached as Exhibits E and F are letters dated July 31, 2000, and August 3, 2000, between counsel for the parties that relate to these discovery discussions. Attached as Exhibit G is Gen-Probe's response to Vysis's second set of document requests, of which Requests Nos. 3-5, 7, 21, 23-25, and 31-41 are relevant.

11. According to publicly available information, Gen-Probe is a wholly-owned subsidiary of Chugai, a large Japanese pharmaceutical company. Mr. R. William Bowen, Jr. is its general counsel. It is my understanding that he oversees all legal matters for Gen-Probe and has a role in advising the company on planning, policy, future product development and other company-wide decisions. Mr. Peter R. Shearer is Gen-Probe's Vice President [of] Patents and I understand that he manages all of Gen-Probe's patent prosecution and plays a major role in protecting its intellectual property interests. I understand Christine A. Gritzmacher to be an in-house attorney for Gen-Probe who prosecutes patents.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that this declaration was executed on the 29th day of August, 2000, at Downers Grove, Illinois.

Norval B. Galloway

Norval B. Galloway

Exhibit	Description	Page
A	November 24, 1995 Stipulated Protective Order re Confidential Information in Gen-Probe, Inc. v. Amoco Corp., Case No. 95-CV-998-J (BTM).	6
B	March 29, 1999 letter from J.L. Bishop to H.L. Nordhoff.	20
C	March 29, 1999 fax letter from H.L. Nordhoff to J.L. Bishop.	24
D	April 9, 1999 letter from J.L. Bishop to H.L. Nordhoff.	29
E	July 31, 2000 letter from Thomas W. Banks to Patrick M. Maloney.	31
F	August 3, 2000 letter from Patrick M. Maloney to Thomas W. Banks.	33
G	June 20, 2000 Gen-Probe's responses to Vysis' Second Set of Requests for Production of Documents.	37

EXHIBIT A

LYON & LYON
A Partnership Including
DOUGLAS E. OLSON (State Bar No. 38649)
A Professional Corporation
MARY S. CONSALVI (State Bar No. 130966)
MATTHEW W. KNIGHT (State Bar No. 150209)
F.T. ALEXANDRA MAHANEY (State Bar No. 125984)
4250 Executive Square, Suite 660
La Jolla, California 92037
(619) 552-8400

Attorneys for Plaintiff
GEN-PROBE INCORPORATED

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED, a Delaware Corporation Plaintiff, v. AMOCO CORPORATION, an Indiana Corporation, AMOCO TECHNOLOGY COMPANY, a Delaware Corporation, GENE-TRAK SYSTEMS, INC., a Delaware Corporation, and VYSIS, INC., a Delaware Corporation, Defendants.	Case No. 95-CV-998-J (BTM) **STIPULATED PROTECTIVE ORDER RE CONFIDENTIAL INFORMATION**

WHEREAS, the discovery and pretrial phase of this action will involve disclosure of trade secrets and other confidential and proprietary business, technical and financial information, the parties hereby stipulate and request that the Court enter the following order pursuant to Rule 26(c) of the Federal Rules of Civil Procedure:

party, is or is not entitled to particular protection or that such information does or does not embody trade secrets of any party. The procedures set forth herein shall not affect the rights of the parties to object to discovery on grounds other than those related to trade secrets or proprietary information claims, nor shall it relieve a party of the necessity of proper response to discovery devices. This order is absolutely without prejudice to claims of waiver by persons who are asserted by persons not a party to this order

16. No Probative Value. This Protective Order shall not abrogate or diminish any contractual, statutory or other legal obligation or right of any party or person with respect to any Confidential Information. The fact that information is designated "CONFIDENTIAL INFORMATION" under this Protective Order shall not be deemed to be determinative of what a trier of fact may determine to be confidential or proprietary. This Order shall be without prejudice to the right of any party to bring before the Court the question of: (i) whether any particular material is or is not confidential; (ii) whether any particular information or material is or is not entitled to a greater or lesser degree of protection than provided hereunder; or (iii) whether any particular information or material is or is not relevant to any issue of this case, provided that in doing so the party complies with the foregoing procedures. Absent a stipulation of all parties, the fact that information has been designated "CONFIDENTIAL" or "CONFIDENTIAL -- FOR COUNSEL EYES ONLY" under this Order shall not be admissible during the trial of this action, nor shall the jury be advised of such designation. ~~The fact that any information is disclosed, used or produced in discovery or trial herein shall not be construed admissible, or offered in any action or proceeding~~

LYON & LYON
4250 EXECUTIVE SQUARE, SUITE 660
LA JOLLA, CA 92037
(619) 552-8400

~~before any court, agency or tribunal as evidence of or concerning whether or not such information is confidential or proprietary.~~

17. Return of Information. At the conclusion of this action whether by judgment and exhaustion of all appeals, or by settlement, all Confidential Information and all documents which reflect such information shall be (i) delivered to the party that furnished such Confidential Information, or (ii) in lieu of delivery to the furnishing party, destroyed, in which event counsel shall give written notice of such destruction to opposing counsel. The attorneys of record shall insure that all the Confidential Information in the possession, custody or control of their experts and consultants is also destroyed or returned to the party that furnished such Confidential Information. In no event shall a party, their experts or consultants retain a copy of Confidential Information produced to it.

18. Court's Jurisdiction. The Court retains jurisdiction to make such amendments, modifications, deletions and additions to this Order as the Court may from time to time deem appropriate. The provisions of this Order regarding the use and/or disclosure of Confidential Information and Confidential -- For Counsel Only information shall survive the termination of this action, and the Court shall retain jurisdiction with respect to this Order.

19. Jurisdictional Effect. An entity's stipulation to this Protective Order shall have no effect on that entity's right to file a motion under Fed. R. Civ. P. 12 or challenge this Court's jurisdiction over said entity.

///

///

LYON & LYON
4250 EXECUTIVE SQUARE, SUITE 660
LA JOLLA, CA 92037
(619) 552-8400

20. Third Party Rights. This order is without prejudice to the rights of any third party.

LYON & LYON

Dated: Oct 20 1995

By: Mary Consalvi
MARY S. CONSALVI
Attorneys for Plaintiff,
GEN-PROBE INCORPORATED

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER

Dated: ~~November~~ November 8, 1995

By: Gerson S. Panitch
GERSON S. PANITCH
Attorneys for Defendants,
AMOCO CORPORATION, AMOCO TECHNOLOGY
COMPANY, GENE-TRAK SYSTEMS, INC.
and VYSIS, INC.

WRIGHT & L'ESTRANGE

Dated: Nov. 10, 1995

By: John H. L'Estrange Jr.
Co-Counsel for Defendants,
AMOCO CORPORATION, AMOCO TECHNOLOGY
COMPANY, GENE-TRAK SYSTEMS, INC.
and VYSIS, INC.

ORDER

IT IS SO ORDERED as modified in writing by the Court

Dated: ~~October~~ November 23, 1995

UNITED STATES ~~DISTRICT~~ JUDGE
Magistrate

EXHIBIT B

VYSIS

March 29, 1999

BY FACSIMILE

Gen-Probe Incorporated
10210 Genetic Center Drive
San Diego, CA 92121-4362

Attention: H.L. Nordhoff, President &
Chief Executive Officer

Settlement Proposal

Dear Hank:

Thank you for meeting with us last Wednesday. We remain hopeful that an acceptable settlement can be found so that our companies can get on with their main business activities. Thus, as agreed, we have developed the attached alternative settlement proposal for your review and consideration.

We look forward to receiving Gen-Probe's proposal.

Best regards,

J.L. Bishop,
President and CEO
Attach.

AMOCO SETTLEMENT PROPOSAL

A. PATENT CASES

1. The Amoco defendants will agree not to challenge directly or indirectly the validity of the Kohne '330 and '611 patents in the future.

2. Gen-Probe will agree not to challenge directly or indirectly the validity of the Vysis Listeria patent in the future.

3. Gen-Probe will grant Vysis a limited worldwide, nonexclusive, royalty-free immunity from suit for assays for detecting or quantifying ribosomal nucleic acids for food testing applications covered by any claim of the Kohne '330 or '611 patents.

4. Vysis will grant Gen-Probe a worldwide, nonexclusive, royalty-free license under the Listeria patent.

5. Gen-Probe will release the Amoco defendants for alleged past infringement of Gen-Probe patents and dismiss its pending causes of action in the patent case.

6. Vysis will release Gen-Probe for all claims of alleged past infringement of Vysis patents and dismiss its pending causes of action in the patent case.

B. OTHER PATENTS

7. Gen-Probe will be permitted to take a worldwide, nonexclusive license under ribosomal nucleic acid probe patents owned by Vysis (Vysis' probe library) as of the settlement date at a royalty rate of 2% of future sales of products or services covered by the patents to the ultimate consumers or users of such products and services (Net Sales).

8. Vysis will grant to Gen-Probe an option, exercisable within 9 months of the settlement date to acquire a worldwide, nonexclusive license under the RTC patents for a $2 million up-front license fee and a running royalty of 6% of Net Sales made after the settlement date.

9. Vysis will grant to Gen-Probe an option, exercisable within 9 months of the settlement date to acquire a worldwide, nonexclusive license for detecting and quantifying ribosomal nucleic acids under the Stanbridge patent for a royalty of 5% (to be reduced to 3% as partial consideration for this settlement) of Net Sales made after the settlement date.

10. Gen-Probe shall be free at any time, without surrendering its option rights granted above, to mount any challenge to the validity or enforceability of the Stanbridge or RTC patents either as an appropriate proceeding before the U.S. PTO or in the appropriate federal district court. During the course of any such proceeding, Gen-Probe may either repudiate any license(s) it may have acquired under the patent(s) and cease paying royalties, thereby subjecting itself to all appropriate awards of compensatory and punitive damages, costs, attorney fees, and injunctive relief, or may keep the license(s) in force by continuing to pay the royalties due under the agreement. In the event that Gen-Probe's challenge does not result in a judgment that all claims of the relevant patent(s) infringed by Gen-Probe are invalid or unenforceable, the royalty rate under such extant license or option shall be increased by 2% effective as of the date of the trial court or administrative decision to that effect.

C. MALICIOUS PROSECUTION CASES

11. Amoco will pay Gen-Probe, in addition to the considerations listed above, $1 million and Kohne $250,000.

12. Kohne, Gen-Probe and Chugai will grant a general release, including a release of unknown claims, associated with prosecution of the UC and CNS cases and dismiss with prejudice the pending malicious prosecution actions.

D. GENERAL PROVISIONS

13. The licenses and/or immunities provided under the agreement would be transferable only with the sale of the business or of substantially all of the assets to which the business relates. The discounted royalty rate specified in paragraph 9 is personal to Gen-Probe. In the event of the sale of Gen-Probe's business or of substantially all of Gen-Probe's assets to which Gen-Probe's business relates, any surviving license under the Stanbridge patent will include a running royalty of 5%.

14. The terms of the settlement shall be confidential except that the terms of the licenses and/or immunities granted may be disclosed by a party to the extent necessary to comply with applicable securities laws.

EXHIBIT C

Cities
Settlement Discussion
W GP.

GEN-PROBE INCORPORATED
10210 Genetic Center Drive, San Diego, CA 92121
Phone: (619) 410-8902 Fax: (619) 410-8901

Facsimile

Date: March 29, 1999

To: John L. Bishop

From: H. L. Nordhoff

Fax: 630 271 7078

Pages to Follow: 2

Message:

Dear John:

Attached please find our proposal. I know you will give it serious consideration for we are both anxious to get back to business and grow our respective companies. The terms should be viewed together.

I look forward to hearing from you and doing our best to settle this matter.

Sincerely,

H. L. Nordhoff

Transmission Problems (619) 410-8903

RECEIVED TIME MAR 29 8:49PM

Exhibit C
24

OUTLINE OF SETTLEMENT TERMS PROPOSED BY GEN-PROBE

Resolution of litigation

- GP withdraws its patent infringement suit against Amoco/Vysis and releases Amoco/Vysis from claims of past infringement.
- Amoco/Vysis withdraw their patent infringement counterclaim against GP and release GP from claims of past infringement.
- GP withdraws its malicious prosecution suit against Amoco/Vysis and releases Amoco/Vysis from all claims therein in return for a cash payment of $10 million from Amoco/Vysis to GP.
- Amoco/Vysis agree to withdraw from active participation in pending oppositions to the Kohne European patents, including the pending EPO appeal, and agree not to initiate any future proceedings (directly or through any third party) or to induce any third party to initiate any proceedings or provide assistance to any third party in proceedings in any countries challenging the validity or GP's ownership of the Kohne patent rights or any other patent rights of GP relating to the use of nucleic acid probes to detect ribosomal RNA.
- Amoco/Vysis stipulate to the validity of all claims in issued Kohne patents worldwide and stipulate that GP is the rightful legal owner of all Kohne patent rights.

Exchange of intellectual property rights

- GP grants Amoco/Vysis a paid-up, royalty-free, non-exclusive, worldwide license under any claim of the Kohne '330 or '611 patents solely for use in the field of food testing.
- Amoco/Vysis grant GP a paid-up, royalty-free, non-exclusive, worldwide license under any patents owned or controlled by Amoco/Vysis that are directed to the detection of Listeria, including without limitation Stackebrandt.
- Amoco/Vysis grant GP a paid-up, non-exclusive, royalty-free, worldwide license under Collins patents in return for a payment of $5 million.
- Amoco/Vysis grant GP a paid-up, non-exclusive, royalty-free, worldwide sublicense under the Stanbridge patent in consideration of one dollar and other considerations recited herein.
- GP receives a life-of-patent option for a non-exclusive, worldwide license under all Amoco/Vysis patents covering probes for detection of ribosomal RNA sequences. GP may exercise such option with respect to individual patents or groups of patents. Such licenses shall be royalty free for any patent based on an application having an effective filing date after July 25, 1989 and shall bear a commercially reasonable royalty not to exceed 2%, to be negotiated in good faith, for any patent based on an application having an effective filing date before July 25, 1989.

- All licenses granted herein may be sublicensed by the licensee to an affiliate or commercial collaborator or for use in connection with other significant out-licensed technology (provided, that neither party may sublicense such rights to an existing collaborator or licensee of the party granting such license) and may be assigned only in connection with a sale or transfer of essentially all of the licensee's business.

VYSIS

April 9, 1999

BY FACSIMILE

Gen-Probe Incorporated
10210 Genetic Center Drive
San Diego, CA 92121-4362

Attention: H.L. Nordhoff, President &
Chief Executive Officer

Settlement Negotiations

Dear Hank:

We remain interested in pursuing resolution of the various issues pending between our firms. I would like to see if that can be done now that we have already found agreement to some of the patent issues and now that Judge Prager seems to have finalized his ruling on Amoco's Motion for Summary Judgment in the malicious prosecution case. I understand, for example, that Gen-Probe's counsel acknowledged to Judge Prager at the hearing Wednesday that the case was brought to provide Gen-Probe with additional leverage regarding the outstanding patent issues. Although we did not see that the case strengthened Gen-Probe's position, Judge Prager's recent rulings should confirm that any additional leverage and any corresponding damage recovery that Gen-Probe might have expected from it are simply not forthcoming.

At the same time, I think we have already found resolution to many substantial issues regarding our respective patents. Vysis will agree, for example, to forego activities in clinical diagnostics utilizing ribosomal nucleic acids. We will also agree to make our probe library available to Gen-Probe. I think you would agree these represent substantial concessions on our part. In return, Gen-Probe has indicated it will provide us with freedom to operate our Gene-Trak food diagnostics business. Finally, Vysis can also agree that the Collins and Stanbridge patents can be separated from consideration and settlement of the pending litigations. Again, we believe this should simplify matters rather than complicate them.

I had understood that Gen-Probe had decided that further settlement discussions would be unproductive. However, I understand now from Bill's recent letter to Tom Ryan, that Gen-Probe is agreeable to further discussions albeit without Judge Prager's assistance. As I said earlier, we remain interested in resolving the issues between our firms. Given the present postures of the cases and the substantial agreement already reached, we believe further discussions will be useful. And, as you and I agreed during our last meeting in San Diego, it would be far better for each of us to resolve the litigations so that we can refocus our attention on our own businesses.

I look forward to your suggestions as to how best to proceed.

Best regards,

J.L. Bishop,
President and CEO

EXHIBIT D

VYSIS

April 9, 1999

BY FACSIMILE

Gen-Probe Incorporated
10210 Genetic Center Drive
San Diego, CA 92121-4362

Attention: H.L. Nordhoff, President &
Chief Executive Officer

Settlement Negotiations

Dear Hank:

We remain interested in pursuing resolution of the various issues pending between our firms. I would like to see if that can be done now that we have already found agreement to some of the patent issues and now that Judge Prager seems to have finalized his ruling on Amoco's Motion for Summary Judgment in the malicious prosecution case. I understand, for example, that Gen-Probe's counsel acknowledged to Judge Prager at the hearing Wednesday that the case was brought to provide Gen-Probe with additional leverage regarding the outstanding patent issues. Although we did not see that the case strengthened Gen-Probe's position, Judge Prager's recent rulings should confirm that any additional leverage and any corresponding damage recovery that Gen-Probe might have expected from it are simply not forthcoming.

At the same time, I think we have already found resolution to many substantial issues regarding our respective patents. Vysis will agree, for example, to forego activities in clinical diagnostics utilizing ribosomal nucleic acids. We will also agree to make our probe library available to Gen-Probe. I think you would agree these represent substantial concessions on our part. In return, Gen-Probe has indicated it will provide us with freedom to operate our Gene-Trak food diagnostics business. Finally, Vysis can also agree that the Collins and Stanbridge patents can be separated from consideration and settlement of the pending litigations. Again, we believe this should simplify matters rather than complicate them.

I had understood that Gen-Probe had decided that further settlement discussions would be unproductive. However, I understand now from Bill's recent letter to Tom Ryan, that Gen-Probe is agreeable to further discussions albeit without Judge Prager's assistance. As I said earlier, we remain interested in resolving the issues between our firms. Given the present postures of the cases and the substantial agreement already reached, we believe further discussions will be useful. And, as you and I agreed during our last meeting in San Diego, it would be far better for each of us to resolve the litigations so that we can refocus our attention on our own businesses.

I look forward to your suggestions as to how best to proceed.

Best regards,

J.L. Bishop,
President and CEO

EXHIBIT E

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
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July 31, 2000

VIA FACSIMILE

Patrick M. Maloney, Esq.
Cooley Godward LLP
4365 Executive Drive
Suite 1100
San Diego, CA 92121-2128

Re: *Gen-Probe Incorporated v. Vysis, Inc.*

Dear Pat:

Thank you for your July 28, 2000 letter summarizing our telephonic meet and confer of July 26, 2000. For the most part, your letter accurately reflects our discussion. There is, however, one inaccuracy. It is my recollection that you agreed to consider whether the "or associated with" language in paragraph 5(f) of the proposed Protective Order could be removed. Please let me know if you disagree.

In our follow-up July 28, 2000 meet and confer, we discussed whether the parties might agree to a specified person or persons who would have access to Gen-Probe Confidential or Confidential-Attorneys Only information and who would not be precluded from assisting in the prosecution of the '338 patent reissue application. Vysis will consider this possibility.

We also discussed in the July 28 meet and confer Gen-Probe's responses to Vysis document requests. Specifically, we discussed Gen-Probe's responses limiting Gen-Probe's production of documents to its NAT test kits for HCV or HIV. See Gen-Probe responses to requests 3-5, 7, 21, 23-25 and 31-41. You stated your belief that the declaratory judgment complaint related only to HCV and HIV products and that these two were the only imminent commercial NAT kit products. I asked whether Gen-Probe would further amend its complaint if during the pendency of the litigation Gen-Probe introduced NAT test kits for other products. You said you would consider this question.

We also discussed Gen-Probe's objection to producing documents broadly relating to its NAT test kits for HCV or HIV and its response that it would produce "a complete set of non-privileged design specification documents concerning the design and method of operation of such documents." See Gen-Probe responses to Vysis document requests 3-5, 7, 9, 21, 23, and 42-43. We discussed whether Gen-Probe would produce only the final design specification documents or would produce all preliminary design specifications created during product development. We also discussed whether responsive research and development documents such as laboratory notebooks would be produced. You said you would consider these issues.

Finally, we discussed Gen-Probe's response to Document Request No. 6 and whether or not it will produce a sample of its NAT test kits for use in detecting HCV and HIV to Vysis under the terms of the Protective Order. You also wanted to consider this matter further.

We agreed that the parties will not raise issues regarding the scope of discovery with Magistrate Battaglia tomorrow. You raised the notion that we might want to obtain the magistrate's views on issues relating to the Protective Order, particularly paragraph 5. As we discussed on Friday, we are presently doing legal research on issues raised by paragraph 5 and will consider the cases you brought to our attention. After we complete the legal research, we will consider a compromise to your proposed paragraph 5. This is an important issue for Vysis because it impacts Vysis's ability to defend this lawsuit and to effectively prosecute the reissue application. Accordingly, we will most likely not be in a position to propose any alternative to paragraph 5 until the end of this week.

Please let me know if I have misstated or misunderstood any point from our meet and confer discussions. I'd like to thank you and Matt for the spirit of cooperation displayed during these discussions.

Sincerely,

Thomas W. Banks

TWB/sls

EXHIBIT F

Cooley Godward LLP

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PATRICK M. MALONEY
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August 3, 2000

VIA FACSIMILE

Thomas W. Banks, Esq.
Finnegan, Henderson, Farabow, et al.
700 Hansen Way
Palo Alto, CA 94304

Re: Gen-Probe Incorporated v. Vysis, Inc.

Dear Tom:

Thank you for your letter of July 31, 2000, which summarizes our telephone conference of July 28, 2000. I write to add to the record several points not contained in your letter and to clarify certain aspects of your letter.

First, I wish to further elaborate on our discussions concerning the limiting language contained in Gen-Probe's responses to Vysis' document requests 3-5, 7, 9, 21, 23, and 42-43. Specifically, Gen-Probe agreed in its responses to produce all "a complete set of non-privileged design specification documents concerning the design and method of operation of such products." During our meet and confer, you asked whether Gen-Probe intended to produce design and specification documents with respect to each and every iteration of the HIV and HCV test kits or whether Gen-Probe's production would be limited to merely the final, commercialized versions of these products. As I explained, it is Gen-Probe's position that the only design and specification documents that are relevant are those that describe the HCV and HIV products that Gen-Probe has commercialized. Thus, Gen-Probe has agreed to produce and will produce documents so that Vysis may evaluate Gen-Probe's claim of non-infringement with respect to its commercial products. Gen-Probe will resist, however, Vysis' efforts to engage in a fishing expedition through Gen-Probe's sensitive and confidential research and development documents and materials, including its laboratory notebooks.

Next, I would like to confirm the agreements we reached with respect to Vysis and the third parties' (Banks; BP Amoco; Galloway; and Finnegan, Henderson) discovery responses. In regards to Vysis and the third parties' (collectively the "responding parties") "effective filing date" objection, the parties still harbor differing opinions about the relevancy of some later created documents. Nevertheless, the responding parties will respond to the affected document requests by producing all responsive documents created before December 21, 1987 and those responsive documents created after December 21, 1987 that refer to documents created or events that occurred before that date. Nothing herein shall be construed as a waiver of Gen-Probe's right to pursue discovery of documents created after December 21, 1987.

Cooley Godward LLP

We also discussed Vysis' responses to Gen-Probe's interrogatories. With respect to interrogatory 2, you acknowledged our position that Gen-Probe is entitled to discover the facts that underlie Vysis' contention, which is set out in paragraph 1 of Vysis' Answer, that Gen-Probe's NAT test kits for the detection of HCV and HIV infringe the claims of the '338 patent. You responded, however, that you would need to discuss this issue further with Charlie Lipsey. Please let us know, as soon as possible, whether Vysis will voluntarily provide such a response. With respect to interrogatories 3 and 4, you agreed that Vysis would provide a further response that would set out at least the information contained in the reissue application. Please provide Vysis' amended responses to all of these interrogatories on or before Friday, August 11, 2000.

Finally, as you will recall, during our conversation, Matt Lehr and I advised you that there are several other discovery issues that we would raise by way of a letter. These issues are set forth below:

The third party witnesses have objected to producing documents that are owned by Vysis and have stated that the documents sought from them will be produced in response to the document requests propounded to Vysis. *See e.g.* Third Party Thomas W. Banks' Objections and Responses to Plaintiff Gen-Probe Incorporated's Subpoena for Production of Documents ("Banks' Subpoena Responses"), General Objection 8. Gen-Probe is entitled to know which of the various persons and entities from which it is seeking discovery are in possession of the documents sought. Thus, please ensure that each responding party produces all of the documents sought, irrespective of whether they are owned and produced by Vysis. Alternatively, we would be willing to consider accepting a collective, single set of Vysis' documents, so long as you also identify by bates number, at the time of production, which of those documents were in the possession of the various third parties at the time that service of Gen-Probe's subpoenas was deemed completed.

Vysis and the third party witnesses have objected to producing documents created after December 22, 1999, which is the date on which the Complaint was filed. *See e.g.* Banks' Subpoena Responses, General Objection 5. Gen-Probe does not seek to discover work-product documents created after this date or require that such documents be identified in a privilege log. Gen-probe does request, however, that Vysis and the third parties produce any and all responsive documents that have been created in the ordinary course of business. Please ensure and confirm that all such documents are produced.

Cooley Godward LLP

Vysis has generally objected to the document requests and interrogatories on the grounds that Gen-Probe is already in possession of the information or documents sought. *See* Objections and Responses to Plaintiff Gen-Probe Incorporated's First Set of Requests for Production of Documents, General Objection 3 ("Vysis Responses To Document Requests"). We are unaware of what information you believe that Gen-Probe already possesses. Thus, we cannot accept this objection as a basis to withhold from discovery any information or documents. Please confirm that no documents or information will be withheld on the basis of this objection.

Vysis and the third parties have narrowed the definition of the "'338 patent" that Gen-Probe set forth in its requests. *See e.g.* Vysis' Responses To Document Requests, General Objection 6. Please confirm that Vysis intends to provide discovery with respect to each of the patent applications and patents that trace their roots to the 922,155 application. Further, it appears that the responding parties have excepted from the scope of discovery the foreign applications and patents that are related to the '338 patent. We cannot accept this limitation and insist that Vysis provide full disclosure with respect to all such foreign applications. Please confirm that no documents are being withheld subject to this objection.

The third party witnesses have objected to producing all documents that refer to Vysis' relationship with BP Amoco and all documents that refer to investment by BP Amoco in Vysis. They have, however, offered to produce representative samples of such documents. *See e.g.* Banks' Subpoena Responses, Response 38. Without waiving its right to later pursue such discovery, Gen-Probe is amenable to accepting such a representative sample of these documents, provided that Vysis prepares and produces a list that describes the material elements of any and all investment by BP Amoco in Vysis or substantial agreements between BP Amoco and Vysis (i.e. partnership agreements, joint venture agreements, collaboration agreements, co-development agreements, licensing agreements, etc.) Please contact us to discuss further such an arrangement.

The third parties have objected to the definition of BP Amoco that Gen-Probe inserted into its subpoenas. *See e.g.* Banks' Subpoena Responses , General Objection 6. The responding parties have excluded from the definition of BP Amoco the following companies: Gene-Trak, Inc., Integrated Genetics, and Gene-Trak Systems Industrial Diagnostics Corporation. It is our understanding that BP Amoco has or had substantial relationships with or investment in these companies, such that BP Amoco was in a position to exercise control over them. Thus, we believe that they should be considered part of BP Amoco for purposes of discovery. If you believe that we are incorrect, please explain the basis for your position. Also, please identify whether documents in the possession, custody or control of BP Amoco are being withheld on this basis.

As a final point, please ensure that all documents that are withheld on the basis of any applicable privilege are identified in an appropriate privilege log.

Cooley Godward LLP

Thomas W. Banks, Esq.
August 3, 2000
Page Four

I sincerely hope that we can continue to work together to resolve these issues in an expeditious fashion. Please do not hesitate to contact us at you earliest convenience to discuss any of the issues identified above. Similarly, if I have misstated any aspect of our telephone conversation of Friday, July 28, 2000, please let me know.

Very sincerely,

Cooley Godward LLP

Patrick M. Maloney

PMM:lh

cc: Stephen P. Swinton, Esq.
Matthew Lehr, Esq.

09685495.080800

EXHIBIT G

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Attorneys for Plaintiff
Gen-Probe Incorporated

6/20

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED, Plaintiff, v. VYSIS, INC., Defendant.	No. 99cv2668 H (AJB) **GEN-PROBE INCORPORATED'S RESPONSES TO VYSIS, INC.'S SECOND SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS**

PROPOUNDING PARTY: **DEFENDANT VYSIS, INC.**

RESPONDING PARTY: **PLAINTIFF GEN-PROBE INCORPORATED**

SET NUMBER: **TWO (2)**

Pursuant to Federal Rule of Civil Procedure 34, Plaintiff Gen-Probe Incorporated ("Gen-Probe") responds as follows to defendant Vysis, Inc.'s second set of requests for production of documents:

I. GENERAL RESPONSES.

1. Gen-Probe's response to defendant's first set of requests for production of documents is made to the best of Gen-Probe's current employees' present knowledge, information, and belief.

Said response is at all times subject to such additional or different information that discovery or further investigation may disclose and, while based on the present state of Gen-Probe's recollection, is subject to such refreshing of recollection, and such additional knowledge of facts, as may result from its further discovery or investigation.

2. Gen-Probe reserves the right to make any use of, or to introduce at any hearing and at trial, documents responsive to defendant's first request for production but discovered subsequent to the date of Gen-Probe's initial production, including, but not limited to, any documents obtained in discovery herein.

3. Gen-Probe will respond to each document request with documents currently in Gen-Probe's possession, custody and control. By stating in these responses that Gen-Probe will produce documents or is searching for documents, Gen-Probe does not represent that any document actually exists, but rather that Gen-Probe will make a good faith search and attempt to ascertain whether documents responsive to defendant's request do, in fact, exist.

4. To the extent that Gen-Probe responds to defendant's document requests by stating that Gen-Probe will produce documents which it or any other party to this litigation deems to embody material that is private, business confidential, proprietary, trade secret or otherwise protected from disclosure pursuant to Federal Rule of Civil Procedure 26(c)(7), Federal Rule of Evidence 501, California Evidence Code section 1060, California Constitution, Article I, section 1, or any like or similar law of any jurisdiction, Gen-Probe will do so only upon the entry of an appropriate protective order.

5. Gen-Probe reserves the right to decide whether the documents produced for inspection shall be produced as they are kept in the usual course of business or shall be organized and labeled to correspond with the categories in defendant's request, in accordance with Federal Rule of Civil Procedure 34(b).

6. Gen-Probe reserves all objections or other questions as to the competency, relevance, materiality, privilege or admissibility as evidence in any subsequent proceeding in or trial of this or any other action for any purpose whatsoever of this response and any document or thing produced in response to defendant's request.

7. Gen-Probe reserves the right to object on any ground at any time to such other or supplemental requests for production as defendant may at any time propound involving or relating to the subject matter of these requests.

8. Subject to all objections, privileges and other exceptions stated herein, Gen-Probe shall produce the documents requested in defendant's second request for production of documents at the offices of its counsel, Cooley, Godward LLP, 4365 Executive Drive, 12th Floor, San Diego, California, after an appropriate protective order has been entered.

II. GENERAL OBJECTIONS.

1. Gen-Probe makes the following general objections, whether or not separately set forth in response to each document request, to each and every instruction, definition, and document request made in defendant's first request for production of documents:

2. Gen-Probe objects generally to Request 2 through 48, insofar as any of them seeks production of documents or information protected by the attorney-client privilege or the attorney work product privilege. Such documents or information shall not be produced in response to defendant's request, and any inadvertent production thereof shall not be deemed a waiver of any privilege with respect to such documents or information or of any work product doctrine, which may attach thereto.

3. Gen-Probe objects to the introductory definitions and instructions to defendant's document request to the extent said definitions or instructions purport to enlarge, expand, or alter in any way the plain meaning and scope of any specific request on the ground that such enlargement, expansion, or alteration renders said request vague, ambiguous, unintelligible, unduly broad, and uncertain.

4. Gen-Probe objects to all instructions, definitions and document requests to the extent they seek documents not currently in Gen-Probe's possession, custody or control, or refer to persons, entities or events not known to Gen-Probe, on the grounds that such instructions, definitions, or requests seek to require more instructions, definitions, or requests seek to require more of Gen-Probe than any obligation imposed by law, would subject Gen-Probe to unreasonable and undue annoyance, oppression, burden, and expense, and would seek to impose upon Gen-

Probe an obligation to investigate or discover information or materials from third parties or sources who are equally accessible to defendant.

5. Gen-Probe objects to all definitions, instructions, and document requests in which the phrase "relate to" or "relating to" appears. The terms "relate to" and "relating to" are overly broad, vague, ambiguous, and unintelligible, require subjective judgment on the part of Gen-Probe and Gen-Probe attorneys, and would require a conclusion or opinion of counsel in violation of the attorney work product doctrine. Without waiving this objection, and subject to all other applicable objections or privileges stated herein, Gen-Probe will produce, in response to any request for documents that "relate" to a given subject, such documents as expressly reflect or refer on their face to information relevant to the specified subject.

6. Gen-Probe objects to Definition C to the extent it defines "Gen-Probe" to include Gen-Probe's predecessors or successors; past or present divisions, subsidiaries, parents, or affiliates of any of the foregoing entities; past or present joint ventures, partnerships, or limited partnerships of which any of the foregoing entities is a joint venturer or a limited or general partner; and past or present directors, officers, employees, agents, or representatives of any of the foregoing entities. Said definition is vague and ambiguous in that it cannot be determined what is meant by the term "Gen-Probe." Said definition is also overly broad, seeks irrelevant information not calculated to lead to the discovery of admissible evidence, and would subject Gen-Probe and the other entities identified in the definition to unreasonable and undue annoyance, oppression, burden and expense.

7. Gen-Probe objects to Definition H to the extent that it defines the terms "product," "products," "process" and "processes" in such a manner that they are interchangeable with one another and to the extent that said definition embraces products and processes other than those described in the operative pleading.

8. Gen-Probe further objects to Definition I to the extent that it defines the phrase "target capture" more broadly than technology taught by the '338 patent.

9. Gen-Probe objects to the Definitions, Instructions, and prefatory statement, on the ground that they seek unilaterally to impose an obligation to provide supplemental information greater than that required by the Federal Rules of Civil Procedure and would subject Gen-Probe to

unreasonable and undue annoyance, oppression, burden, and expense.

10. Gen-Probe objects to the statement in Instructions A and C and Definition C to the extent they seek to require Gen-Probe to search for information about documents no longer in existence or in Gen-Probe's possession, custody or control, on the grounds that said instruction is overly broad, would subject Gen-Probe to undue annoyance, oppression, burden, and expense, and seeks to impose upon Gen-Probe an obligation to investigate information or materials from third parties or services who are equally accessible to defendant.

11. Gen-Probe objects to Instruction A to the extent it seeks to require it to identify anything other than the specific claim of privilege or work product being made and the grounds for such claim, on the ground that defendant's requests encompass potentially thousands of pages of documents stored at Gen-Probe and possibly other locations, not all of which have as yet been identified or reviewed by counsel. Accordingly, said instruction would subject Gen-Probe to unreasonable and undue annoyance, oppression, burden, and expense, and seeks information protected from discovery by privilege and as work product. Without waiving this objection and subject to all other objections, privileges and exceptions set forth herein, Gen-Probe will identify the date, author, and recipient(s) of each document withheld on the basis of privilege or work product.

III. SPECIFIC OBJECTIONS AND RESPONSES TO DOCUMENT REQUESTS.

Without waiving or limiting in any manner any of the foregoing General Objections, but rather incorporating them into each of the following responses to the extent applicable, Gen-Probe responds to the specific requests of defendant's first request for production of documents as follows:

DOCUMENT REQUEST NO. 2:

All documents referred to in, relied on in preparing, or relating to the subject matter of Gen-Probe's Responses to Vysis's Interrogatories 3-9 to Gen-Probe.

RESPONSE TO DOCUMENT REQUEST NO. 2:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further incorporates, as if fully set forth

herein, each of the objections, Gen-Probe set forth in its responses to interrogatories 3 – 9, to the extent that this request incorporates those interrogatories by reference. Gen-Probe further objects to producing documents responsive to that portion of the request seeking documents "relied on in preparing, or relating to the subject matter of Gen-Probe's Responses to Vysis's Interrogatories 3-9 to Gen-Probe" on the ground that such request expressly calls for the production of work product or other privileged information. Gen-Probe also objects that the term "subject matter of Gen-Probe's response" is vague and overbroad. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all non-privileged documents in its possession, custody and control to which it refers in its responses to Vysis's Interrogatories 3-9.

DOCUMENT REQUEST NO. 3:

All documents relating to, referring to, or describing any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 3:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits for use in detecting HCV or HIV, Gen-Probe objects that Vysis' demand for the production of "all documents relating to, referring to, or describing" such products is overbroad and burdensome. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce a complete set of non-privileged, design specification documents concerning the design and method of operation of such products.

DOCUMENT REQUEST NO. 4:

All documents constituting, referring to, or relating to instructions and/or manuals for any

product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 4:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits for use in detecting HCV or HIV, Gen-Probe objects that Vysis' demand for the production of "all documents constituting, referring or relating to instructions and/or manuals" for such products is overbroad and burdensome. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce a complete set of non-privileged, design specification documents concerning the design and method of operation of such products.

DOCUMENT REQUEST NO. 5:

All documents constituting, referring, or relating to product specifications for any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 5:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits for use in detecting HCV or HIV, Gen-Probe objects that Vysis' demand for the production of "all

documents constituting, referring or relating to product specifications" for such products is overbroad and burdensome. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce a complete set of non-privileged, design specification documents concerning the design and method of operation of such products.

DOCUMENT REQUEST NO. 6:

A sample of Gen-Probe's NAT test kits for use in detecting HCV and HIV.

RESPONSE TO DOCUMENT REQUEST NO. 6:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce samples of its NAT test kits to an (1) an independent third party (2) upon the parties' agreement or court order sufficient to invoke restrictions and conditions appropriate to protect Gen-Probe's proprietary interests in these biological materials and ensure the continued integrity of such samples.

DOCUMENT REQUEST NO. 7:

All documents referring to, relating to, or describing the research, development, manufacture, use or sale by Gen-Probe of any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 7:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits for use in detecting HCV or HIV, Gen-Probe objects that Vysis' demand for the production of "all documents referring to, relating to, or describing the research, development, manufacture use or

sale by Gen-Probe" of any such products is overbroad and burdensome. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce a complete set of non-privileged, design specification documents concerning the design and method of operation of such products.

DOCUMENT REQUEST NO. 8:

All documents relating to, referring to, or describing any effort or attempt to design around the '338 patent.

RESPONSE TO DOCUMENT REQUEST NO. 8:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is overbroad, unduly burdensome, and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe also objects that the term "design around" is vague and ambiguous leaving Gen-Probe to guess as to its meaning. Without waiving, and subject to, the foregoing objections, Gen-Probe states that it does not possess any non-privileged documents that are responsive to this request.

DOCUMENT REQUEST NO. 9:

All documents relating to, referring to, or describing comparisons between Gen-Probe's NAT test kits for use in detecting HCV or HIV and any potentially competing product or process not within the scope of the claims of the '338 patent.

RESPONSE TO DOCUMENT REQUEST NO. 9:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that the language "potentially competing product or process not within the scope of the claims of the '338 patent" is vague and ambiguous. Gen-Probe further objects that this request calls for legal conclusions concerning the construction of the claims of the '338 patent and the products or processes that Vysis contends are not within the claims of the '338 patent. Gen-Probe further objects that this request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce a complete set of non-privileged, design specification documents concerning the design

and method of operation of its NAT test kits for HCV and HIV.

DOCUMENT REQUEST NO. 10:

All documents referring or relating to the '338 patent or any related patent or application.

RESPONSE TO DOCUMENT REQUEST NO. 10:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that the term "related patent or application" is vague and ambiguous, leaving Gen-Probe to guess as to its meaning. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all non-privileged, responsive documents within its possession, custody, and control that refer to the '338 patent.

DOCUMENT REQUEST NO. 11:

All documents referring to, relating to, or describing any analysis or study of the '338 patent.

RESPONSE TO DOCUMENT REQUEST NO. 11:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all non-privileged, responsive documents within its possession, custody, and control.

DOCUMENT REQUEST NO. 12:

All documents that Gen-Probe believes support its contention that it does not infringe the '338 patent.

RESPONSE TO DOCUMENT REQUEST NO. 12:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that Vysis' request for all documents "supporting" Gen-Probe's contentions expressly requires the disclosure of attorney work product and privileged attorney client communications. Gen-Probe further objects to this request to the extent that it prematurely seeks the facts and contentions that Gen-Probe will advance at trial before the completion of investigation and discovery. In response to this request

and at present time, Gen-Probe will produce those documents that are also responsive to Vysis' document requests 1-3, 6, 9, 11, 16, 24 and 32 and respond to interrogatory 2. Upon satisfactory progress of discovery, Gen-Probe will produce all documents then within its possession, custody and control that are responsive to Vysis' requests for such contention discovery.

DOCUMENT REQUEST NO. 13:

All documents that Gen-Probe believes support its contention that the '338 patent is invalid.

RESPONSE TO DOCUMENT REQUEST NO. 13:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that Vysis' request for all documents "supporting" Gen-Probe's contentions expressly requires the disclosure of attorney work product and privileged attorney client communications. Gen-Probe further objects to this interrogatory to the extent that it prematurely seeks the facts and contentions that Gen-Probe will advance at trial before the completion of investigation and discovery. In response to this request and at present time, Gen-Probe will produce those documents that are also responsive to Vysis' document requests 1-3, 6, 9, 11, 16, 24, and 32 and respond to interrogatory 1. Upon satisfactory progress of discovery, Gen-Probe will produce all documents then within its possession, custody and control that are responsive to Vysis' requests for such contention discovery.

DOCUMENT REQUEST NO. 14:

All documents that Gen-Probe believes support its contention that the '338 patent is unenforceable, including each unenforceability contention advanced by Gen-Probe in briefing on Vysis' motion for a stay of these proceedings.

RESPONSE TO DOCUMENT REQUEST NO. 14:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that Vysis' request for all documents "supporting" Gen-Probe's contentions expressly requires the disclosure of attorney work product and privileged attorney client communications. Gen-Probe further objects to this interrogatory to the extent that it prematurely seeks the facts and contentions that Gen-Probe will

advance at trial before the completion of investigation and discovery. In response to this request and at present time, Gen-Probe will produce those documents that are also responsive to Vysis' document requests 1-3, 6, 9, 11, 16, 24 and 32 and respond to interrogatories 1-3, 7, and 9. Upon satisfactory progress of discovery, Gen-Probe will produce all documents then within its possession, custody and control that are responsive to Vysis' requests for such contention discovery.

DOCUMENT REQUEST NO. 15:

All documents on which Gen-Probe relies for its contention that the '338 patent is invalid under 35 U.S.C. §§ 102 or 103.

RESPONSE TO DOCUMENT REQUEST NO. 15:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that Vysis' request for all documents "supporting" Gen-Probe's contentions expressly requires the disclosure of attorney work product and privileged attorney client communications. Gen-Probe further objects to this interrogatory to the extent that it prematurely seeks the facts and contentions that Gen-Probe will advance at trial before the completion of investigation and discovery. In response to this request and at present time, Gen-Probe will produce those documents that are also responsive to Vysis' document requests 1-3, 6, 9, 11, 16, 24, and 32 and respond to interrogatory 1. Upon satisfactory progress of discovery, Gen-Probe will produce all documents then within its possession, custody and control that are responsive to Vysis' requests for such contention discovery.

DOCUMENT REQUEST NO. 16:

All documents referring to, relating to, constituting or describing prior art searches with respect to the subject matter of the '338 patent or the results of such searches.

RESPONSE TO DOCUMENT REQUEST NO. 16:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects to this interrogatory to the extent that it prematurely seeks the facts and contentions that Gen-Probe will advance at trial before the completion of investigation and discovery. Gen-Probe further objects to this request to

the extent that it the criteria employed when searching for prior art constitutes attorney work product. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all non-privileged, prior art references within its possession, custody, and control.

DOCUMENT REQUEST NO. 17:

All documents referring or relating to the scope, meaning, or construction of any claim of the '338 patent.

RESPONSE TO DOCUMENT REQUEST NO. 17:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that Vysis' request for all documents referring or relating to the scope, meaning, or construction of any claim of the '338 patent expressly requires the disclosure of attorney work product and privileged attorney client communications. Gen-Probe further objects to this interrogatory to the extent that it prematurely seeks the facts and contentions that Gen-Probe will advance at trial before the completion of investigation and discovery. In response to this request, at present time, and without waiving, and subject to, the foregoing objections, Gen-Probe will produce those non-privileged documents that are also responsive to Vysis' document requests 1-3, 6, 9, 11, 16, 24, and 32 and respond to interrogatories 1 and 2. Upon satisfactory progress of discovery, Gen-Probe will produce all non-privileged documents then within its possession, custody and control in response to this request.

DOCUMENT REQUEST NO. 18:

All documents referring to, relating to, or constituting any infringement, non-infringement, validity, invalidity, enforceability, or unenforceability analysis of the '338 patent.

RESPONSE TO DOCUMENT REQUEST NO. 18:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Without waiving, and subject to, the foregoing objections, Gen-Probe states that it does not possess any non-privileged documents that are responsive to this request.

DOCUMENT REQUEST NO. 19:

All documents referring to, relating to, or describing any decision about whether to obtain a

legal opinion relating to the '338 patent.

RESPONSE TO DOCUMENT REQUEST NO. 19:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that the term "legal opinion" is vague and ambiguous leaving Gen-Probe to guess as to its meaning. Without waiving, and subject to, the foregoing objections, Gen-Probe states that it does not possess any non-privileged documents that are responsive to this request.

DOCUMENT REQUEST NO. 20:

All documents referring to, relating to, describing, or constituting procedures, policies, guidelines, training materials, or recommended courses of action concerning third-party patents.

RESPONSE TO DOCUMENT REQUEST NO. 20:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe states that it does not possess any non-privileged documents that are responsive to this request.

DOCUMENT REQUEST NO. 21:

All documents referring to, relating to, or describing the use or prospective use of any teaching contained in the '338 patent in the design or development of any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe NAT test kit for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 21:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the terms "amplification" and "teaching." Gen-Probe further objects that this request is phrased in an argumentative manner that assumes facts not in evidence. Gen-Probe still further objects that this request requires Gen-Probe to guess as to the "teaching"

purportedly contained in the '338 patent. Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits for use in detecting HCV or HIV, Gen-Probe objects that Vysis' demand for the production of "all documents referring to, relating to, or describing the use or prospective use of any teaching contained in the '338 patent" is overbroad and burdensome. Without waiving, and subject to, the foregoing objections, and without any agreement or acknowledgement as to the "teaching" of the '338 patent or the use or prospective use of the same, Gen-Probe will produce a complete set of non-privileged, design specification documents concerning the design and method of operation of such products.

DOCUMENT REQUEST NO. 22:

All documents referring to, relating to, or describing the circumstances under which Gen-Probe first became aware of the '338 patent.

RESPONSE TO DOCUMENT REQUEST NO. 22:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe produce all non-privileged, responsive documents within its possession, custody and control.

DOCUMENT REQUEST NO. 23:

All documents referring to, relating to, or describing products or processes for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to all documents referring to, relating to, describing or constituting a study or analysis of those products or processes in relation to the '338 patent.

RESPONSE TO DOCUMENT REQUEST NO. 23:

Gen-Probe incorporates into this response each of the foregoing General Responses and

General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits for use in detecting HCV or HIV, Gen-Probe objects that Vysis' demand for the production of "all documents referring to, relating to, or describing products or processes for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe" is overbroad and burdensome. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce a complete set of non-privileged, design specification documents concerning the design and method of operation of such products.

DOCUMENT REQUEST NO. 24:

All documents referring to, relating to, describing or constituting communications between Gen-Probe and third parties regarding the '338 patent.

RESPONSE TO DOCUMENT REQUEST NO. 24:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects that this request seeks documents that may be protected by the confidentiality interests of third parties and may also be protected by joint and several interests in applicable attorney-client privileged communications and attorney work product. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all non-privileged, responsive documents within its possession, custody, and control that refer both to the '338 patent and Gen-Probe's NAT test kits for HCV and HIV.

DOCUMENT REQUEST NO. 25:

All documents referring to, relating to, describing or constituting communications between Gen-Probe and third parties regarding any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or

with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 25:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request seeks documents that may be protected by the confidentiality interests of third parties. Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Without waiving, and subject to, the foregoing objections, Gen-Probe will produce any non-privileged, responsive documents within its possession, custody, and control.

DOCUMENT REQUEST NO. 26:

All documents referring to, relating to, describing or constituting communications between Gen-Probe and third parties relating to this litigation.

RESPONSE TO DOCUMENT REQUEST NO. 26:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request seeks documents that may be protected by the confidentiality interests of third parties and may also be protected by community of interests in applicable attorney-client privileged communications and attorney work product. Furthermore, Gen-Probe objects to producing or identifying communications occurring after the initiation of the litigation between it and third parties concerning this litigation on the grounds of the attorney-client privilege and attorney work product. Without waiving, and subject to, the foregoing objections, Gen-Probe states that it does not possess any non-privileged documents responsive to this request that pre-date this litigation.

DOCUMENT REQUEST NO. 27:

All documents referring to, relating to, or describing the need for or desirability of Gen-Probe's taking a license under the '338 patent, or Gen-Probe's decision regarding whether or not to

take a license under the '338 patent.

RESPONSE TO DOCUMENT REQUEST NO. 27:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Without waiving, and subject to, the foregoing objections, Gen-Probe states that it does not possess any non-privileged documents that are responsive to this request.

DOCUMENT REQUEST NO. 28:

All documents referring to, relating to, or describing Gen-Probe's decision whether or not to institute this action against Vysis.

RESPONSE TO DOCUMENT REQUEST NO. 28:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Without waiving, and subject to, the foregoing objections, Gen-Probe states that it does not possess any non-privileged documents that are responsive to this request.

DOCUMENT REQUEST NO. 29:

All documents Gen-Probe believes support its unfair competition claim.

RESPONSE TO DOCUMENT REQUEST NO. 29:

Gen-Probe further objects to this request to the extent that it calls for the disclosure of attorney work product. Gen-Probe further objects that Vysis' requests that seek all documents "supporting" Gen-Probe's contentions expressly requires the disclosure of attorney work product and privileged attorney client communications. Gen-Probe further objects to this request to the extent that it prematurely seeks the facts and contentions that Gen-Probe will advance at trial before the completion of investigation and discovery. Upon satisfactory progress of discovery, Gen-Probe will agree to produce all non-privileged documents response to Vysis' request. Without waiving and subject to the foregoing objections, Gen-Probe will produce documents responsive to Vysis' requests document requests 1-3, 6, 9, 11, 16, 24 and 32, and interrogatories 1-3, 7, and 9.

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DOCUMENT REQUEST NO. 30:

Documents sufficient to describe the corporate and organizational structure of Gen-Probe Incorporated for each year since 1990.

RESPONSE TO DOCUMENT REQUEST NO. 30:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce documents that describe its corporate and organizational structure.

DOCUMENT REQUEST NO. 31:

Documents sufficient to identify all employees, attorneys, officers, consultants or other persons involved in the research, development, testing, evaluation, manufacture, marketing, sale, or servicing of any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 31:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Without waiving, and subject to, the foregoing objections, Gen-Probe will prepare and produce a list identifying the persons principally involved with Gen-Probe's NAT test kits for detecting HCV and HIV.

DOCUMENT REQUEST NO. 32:

All documents relating to correspondence or communications between Gen-Probe and Vysis relating to the '338 patent or any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting

HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 32:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all non-privileged, responsive documents in its possession, custody and control that refer both to the '338 patent and Gen-Probe's NAT test kits for HCV and HIV.

DOCUMENT REQUEST NO. 33:

All documents referring to, relating to, describing or constituting offers for sale of any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 33:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all of the non-privileged books and records otherwise available to Vysis under paragraph 3.9 of the parties' license agreement.

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DOCUMENT REQUEST NO. 34:

All documents referring to, relating to, describing or constituting sales of any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 34:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all of the non-privileged books and records otherwise available to Vysis under paragraph 3.9 of the parties' license agreement.

DOCUMENT REQUEST NO. 35:

All documents referring to, relating to, or describing the price of any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 35:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits

for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all of the non-privileged books and records otherwise available to Vysis under paragraph 3.9 of the parties' license agreement.

DOCUMENT REQUEST NO. 36:

All documents referring to, relating to, or describing the costs associated with any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 36:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all of the non-privileged books and records otherwise available to Vysis under paragraph 3.9 of the parties' license agreement.

DOCUMENT REQUEST NO. 37:

All documents referring to, relating to, or describing the profits (gross and net) made on the sale of any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 37:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague

and ambiguous with respect to the term "amplification." Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all of the non-privileged books and records otherwise available to Vysis under paragraph 3.9 of the parties' license agreement.

DOCUMENT REQUEST NO. 38:

All documents referring to, relating to, or describing any licenses, agreements, or contracts involving any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 38:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Without waiving, and subject to, the foregoing objections, Gen-Probe will produce a copy of the license and collaboration agreements with Chiron and Bayer concerning Gen-Probe's NAT test kits for use in detecting HCV and HIV.

DOCUMENT REQUEST NO. 39:

All documents referring to, relating to, or describing any payments paid or received in relation to any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

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RESPONSE TO DOCUMENT REQUEST NO. 39:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Even as to Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all of the non-privileged books and records otherwise available to Vysis under paragraph 3.9 of the parties' license agreement.

DOCUMENT REQUEST NO. 40:

All documents referring to, relating to, describing or constituting business plans, marketing plans or studies, and projections for any product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 40:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects that this request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all non-privileged marketing plans concerning Gen-Probe's NAT test kits for use in detecting HCV and HIV.

DOCUMENT REQUEST NO. 41:

All documents referring to, relating to, describing or constituting patents or applications, U.S. or foreign, owned by or applied for by Gen-Probe, or employees thereof, relating to a product or process for detecting and/or quantifying a polynucleotide using target capture and amplification, including but not limited to, invention disclosures, evaluations of patentability, patent applications and drafts thereof, file wrappers, prosecution histories, and other papers prepared during the course of the prosecution of any such application.

RESPONSE TO DOCUMENT REQUEST NO. 41:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe also objects that to the extent this request seeks documents relating to products other than Gen-Probe's NAT test kits for use in detecting HCV or HIV, the request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects that this request is unduly burdensome to the extent that the information sought is publicly available to Vysis. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Without waiving, and subject to, the foregoing objections, Gen-Probe will produce all responsive, non-privileged documents within its possession, custody and control that refer to or constitute patents or patent applications that claim the inventions that may encompass all or a portion of Gen-Probe's NAT test kits for use in detecting HCV and HIV.

DOCUMENT REQUEST NO. 42:

Documents sufficient to identify any assay made, used, offered for sale, or sold by Gen-Probe for detecting and/or quantifying a polynucleotide using target capture and amplification, other than Gen-Probe's NAT test kits for use in detecting HCV or HIV.

RESPONSE TO DOCUMENT REQUEST NO. 42:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe further objects that this request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery

of admissible evidence. Without waiving and subject to the foregoing objections, Gen-Probe will produce a complete set of non-privileged, design specification documents concerning the design and method of operation of Gen-Probe's NAT test kits for use in detecting HCV or HIV.

DOCUMENT REQUEST NO. 43:

All documents relating to any investigational purpose associated with any sale or offer to sell any goods or services relating to a product or process for detecting and/or quantifying a polynucleotide using target capture and amplification developed by Gen-Probe, either by itself or with another person, including but not limited to Gen-Probe's NAT test kits for use in detecting HCV or HIV, including any document reflecting the nature of any information to be gathered, any obligation to report results by Gen-Probe, any limitations on the nature or extent of the use to which the product may be put by the purchaser, and any anticipated future commercial benefit from providing such goods or services to customers.

RESPONSE TO DOCUMENT REQUEST NO. 43:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe further objects that the term "investigational purpose associated with any sale or offer to sell any goods or services relating to a product or process for detecting and/or quantifying a polynucleotide using target capture and amplification" is vague and ambiguous leaving Gen-Probe to guess as to its meaning. Without waiving, and subject to, the foregoing objections, Gen-Probe will produce a complete set of non-privileged, design specification documents concerning the design and method of operation of Gen-Probe's NAT test kits for use in detecting HCV or HIV and the non-privileged books and records subject to paragraph 3.9 of the parties' license agreement concerning the '338 patent.

DOCUMENT REQUEST NO. 44:

All documents evidencing, relating, or referring to the efficacy, efficiency, cost, speed, accuracy, or desirability of assays or methods for detecting and or quantifying a polynucleotide involving either target capture or amplification but not both.

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RESPONSE TO DOCUMENT REQUEST NO. 44:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe further objects that this request is temporally overbroad to the extent that it seeks documents created after the effective filing date of the application that led to the '338 patent. Subject to the temporal limitation and without waiving, and subject to, the other foregoing objections, Gen-Probe will produce non-privileged, responsive documents in its possession, custody and control, that otherwise may constitute prior art.

DOCUMENT REQUEST NO. 45:

All documents evidencing, relating, or referring to alternatives to the technique encompassed by the claims of the '338 patent for detecting or quantifying a polynucleotide.

RESPONSE TO DOCUMENT REQUEST NO. 45:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe also objects on the grounds that the term "technique encompassed by the claims of the '338 patent" is vague and ambiguous leaving Gen-Probe to guess as to its meaning and the scope of such claims. Gen-Probe further objects to this request to the extent that it prematurely seeks the facts and contentions that Gen-Probe may advance at trial before the completion of investigation and discovery. Gen-Probe further objects that this request is temporally overbroad to the extent that it seeks documents created after the effective filing date of the application that led to the '338 patent. Subject to the temporal limitation and without waiving, and subject to, the other foregoing objections, Gen-Probe will produce non-privileged, responsive documents in its possession, custody and control, that otherwise may constitute prior art.

DOCUMENT REQUEST NO. 46:

All documents evidencing, relating, or referring to the feasibility of cloning as an

amplification technique in assays or methods for detecting or quantifying a polynucleotide.

RESPONSE TO DOCUMENT REQUEST NO. 46:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe further objects that this request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects to this request to the extent that it prematurely seeks the facts and contentions that Gen-Probe may advance at trial before the completion of investigation and discovery. Gen-Probe further objects that this request is temporally overbroad to the extent that it seeks documents created after the effective filing date of the application that led to the '338 patent. Subject to the temporal limitation and without waiving, and subject to, the other foregoing objections, Gen-Probe will produce non-privileged, responsive documents in its possession, custody and control, that otherwise may constitute prior art.

DOCUMENT REQUEST NO. 47:

All documents evidencing, relating, or referring to the feasibility of cell-free protein expression as an amplification technique in assays or methods for detecting or quantifying a polynucleotide.

RESPONSE TO DOCUMENT REQUEST NO. 47:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe further objects to this request to the extent that it prematurely seeks the facts and contentions that Gen-Probe may advance at trial before the completion of investigation and discovery. Gen-Probe further objects that this request is temporally overbroad to the extent that it seeks documents created after the effective filing date of the application that led to the '338 patent. Subject to the temporal limitation and without waiving, and subject to, the other foregoing objections, Gen-Probe will produce non-privileged, responsive

documents in its possession, custody and control, that otherwise may constitute prior art.

DOCUMENT REQUEST NO. 48:

All documents evidencing, relating, or referring to the feasibility of reverse transcription of RNA or DNA as an amplification technique in assays or methods for detecting or quantifying a polynucleotide.

RESPONSE TO DOCUMENT REQUEST NO. 48:

Gen-Probe incorporates into this response each of the foregoing General Responses and General Objections as if fully set forth herein. Gen-Probe further objects that this request is overbroad, unduly burdensome and is not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe further objects that this request is vague and ambiguous with respect to the term "amplification." Gen-Probe further objects to this request to the extent that it prematurely seeks the facts and contentions that Gen-Probe may advance at trial before the completion of investigation and discovery. Gen-Probe further objects that this request is temporally overbroad to the extent that it seeks documents created after the effective filing date of the application that led to the '338 patent. Subject to the temporal limitation and without waiving, and subject to, the other foregoing objections, Gen-Probe will produce non-privileged, responsive documents in its possession, custody and control, that otherwise may constitute prior art.

Dated: June 20, 2000

COOLEY GODWARD LLP
STEPHEN P. SWINTON (106398)
JAMES DONATO (146140)
PATRICK M. MALONEY (197844)

GEN-PROBE INCORPORATED
R. WILLIAM BOWEN, JR. (102178)

By: Patrick Maloney for
Stephen P. Swinton

Attorneys for Plaintiff
Gen-Probe Incorporated

PROOF OF SERVICE BY MAIL

I, Liz Hoke, hereby declare:

I am employed in the City of San Diego, County of San Diego, California in the office of a member of the bar of this court at whose direction the following service was made. I am over the age of eighteen years and not a party to the within action. My business address is Cooley Godward LLP, 4365 Executive Drive, Suite 1100, San Diego, California 92121-2128. I am personally and readily familiar with the business practice of Cooley Godward LLP for collection and processing of correspondence for mailing with the United States Postal Service, pursuant to which mail placed for collection at designated stations in the ordinary course of business is deposited the same day, proper postage prepaid, with the United States Postal Service.

On June 20, 2000, I served: GEN-PROBE INCORPORATED'S RESPONSES TO VYSIS, INC.'S SECOND SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS, GEN-PROBE INCORPORATED'S OBJECTIONS TO VYSIS, INC.'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS, GEN-PROBE INCORPORATED'S OBJECTIONS AND RESPONSES TO VYSIS, INC.'S FIRST SET OF INTERROGATORIES; GEN-PROBE INCORPORATED'S OBJECTIONS AND RESPONSES TO VYSIS, INC.'S SECOND SET OF INTERROGATORIES on the interested parties in this action by placing a true copy thereof, on the above date, enclosed in a sealed envelope, following the ordinary business practice of Cooley Godward LLP, for collection and mailing in the United States mail addressed as follows:

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I declare under penalty of perjury under the laws of the State of California that the

EXHIBIT 7

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GEN-PROBE, INCORPORATED

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. 99CV2668H AJB

[PROPOSED] SECOND AMENDED COMPLAINT FOR DECLARATORY RELIEF AND UNFAIR COMPETITION

PLAINTIFF GEN-PROBE ALLEGES:

INTRODUCTION

1. This action concerns the nature and scope of any obligation of plaintiff Gen-Probe Incorporated ("Gen-Probe") to make royalty payments to defendant Vysis, Inc. ("Vysis") pursuant to a patent license agreement between the parties ("the License") in light of the invalidity and non-infringement of United States Patent No. 5,750,338 ("the '338 patent") that is a subject of that

License. As set forth below, Gen-Probe asks this Court to declare the '338 patent invalid and further to declare that Gen-Probe's current and anticipated activities do not infringe any valid claims of the '338 patent. As a corollary to those declarations, Gen-Probe also asks this court to declare its rights and obligations under the terms of the parties' License. Finally, Gen-Probe also seeks relief from Vysis' continuing acts of wrongful and unfair conduct with respect to the '338 patent.

THE PARTIES

2. Gen-Probe was founded in San Diego in 1984 as a small "start up" company, seeking to develop products based on the discoveries of a local research scientist. Over time, Gen-Probe became one of the largest biotechnology firms in San Diego. Gen-Probe now maintains its principal offices and research facilities at 10210 Genetic Center Drive in San Diego, where it employs over 500 scientists and staff. Gen-Probe is organized under the laws of the State of Delaware.

3. Gen-Probe is informed and believes that defendant Vysis, Inc. (hereinafter "Vysis" or "the defendant") is a corporation organized and incorporated under the laws of the State of Delaware. Gen-Probe is further informed and believes that Vysis maintains its principal place of business in Downers Grove, Illinois and that it is controlled by BP Amoco, Inc.

JURISDICTION AND VENUE

4. Counts One and Two of this Complaint seek declaratory relief under the Declaratory Judgment Act, Title 28, United States Code, Sections 2201 and 2202. This Court has subject matter jurisdiction of the claims asserted thereunder by reason of Title 28, United States Code, Sections 1331, 1338(a), 1338(b) and 1367.

5. Venue is proper in this District under Title 28, United States Code, Sections 1391(b) and 1400(b).

BACKGROUND

6. Living cells store genetic information in molecules of nucleic acid known as DNA. These molecules consist of long, thin, chain-like strands which, in turn, are usually found in the form of two tightly bound, complementary chains. DNA molecules retain their genetic information

in the form of a genetic code. The information in the DNA determines the life processes of each organism. The information in the DNA is used to make related nucleic acid molecules called RNA that cells use to manufacture proteins.

7. Through the work of its scientists and staff, Gen-Probe has developed and continues to develop diagnostic tests that seek out the DNA or RNA of the infectious organisms. These types of tests are generally referred to as "genetic probes" or "nucleic acid tests" ("NAT"). Gen-Probe now markets DNA probe products that test for a wide range of microorganisms that cause tuberculosis, strep throat, pneumonia, fungal infections and sexually transmitted diseases. Through the efforts of its scientists and staff, Gen-Probe has emerged as the recognized world leader in the development, manufacture and commercialization of diagnostic products based on its patented genetic probe technology. Gen-Probe has received over 40 FDA clearances and approvals for genetic probe tests to detect a wide range of microorganisms, including Chlamydia trachomatis, Mycobacterium tuberculosis and Neisseria gonorrhoeae.

8. Many human diseases are caused by bacterial or viral agents that invade living cells. Historically, the presence of these bacterial or viral agents was detected directly by time-consuming methods such as culture or indirectly through the detection of antibodies. Unfortunately, it takes time, sometimes weeks or months, to grow organisms in culture, and it usually takes months for the body to manufacture antibodies in sufficient amounts to reveal the presence of infectious agents. Consequently, these methods do not lend themselves to early detection of infection. NAT addresses this problem.

9. Among the disease detection technologies recently applied by Gen-Probe is its patented nucleic acid technology known as "Transcription-Mediated Amplification" ("TMA"). This technology enables Gen-Probe's NAT products to detect extraordinarily small quantities of the nucleic acids of infectious agents.

10. In September 1996, Gen-Probe received a $7.7 million grant from the National Institutes of Health to develop TMA-based nucleic acid tests to be used in screening donated blood for and human immunodeficiency virus (HIV), the causative agent of AIDS, and hepatitis C virus (HCV), which causes a severe form of hepatitis.

11. At the time of the NIH grant to Gen-Probe, donated blood was principally tested by procedures that detected the presence of antibodies to the viruses being screened. Due to the time it takes for the body to make antibodies after initial infection, donated blood may test negative for antibodies, yet still carry infectious viruses. This delay between the time of actual infection and the time that antibodies can first be detected is often known as the "window period." Reduction of this "window period" was a significant concern of the United States government and the primary focus of the grant to Gen-Probe to develop NAT diagnostics for use in blood screening.

12. In fulfilling its obligations under the grant, Gen-Probe developed NAT tests to detect the DNAs of HIV and hepatitis C in blood. Through the use of its NAT test, Gen-Probe believes that researchers and medical personnel may rapidly and *directly* detect the presence of genetic material of viruses like HIV and HCV more accurately and without the complications and delay associated with conventional *indirect* tests. As such, Gen-Probe believes that its new test may significantly reduce the "window period" for detection of these extremely harmful viral agents and resulting diseases.

13. Final development of the NAT tests for blood screening in the United States is now taking place in testing conducted by the American Red Cross, America's Blood Centers, and others. ("A Purity Quest; Local Biotech's Ultra-Sensitive Blood Screening Could Cut Risk of AIDS, Hepatitis," *San Diego Union*, March 25, 1999, page C-1.) Use of the tests in the United States is made pursuant to an Investigational New Drug Application filed with the United States Food and Drug Administration. In blood tested by the American Red Cross, Gen-Probe's products have detected hepatitis C and HIV which escaped detection by prior methods. ("New Blood Screening Finds Virus Others Missed; Experimental Test Turns Up Hepatitis C In Donated Blood," *San Diego Union*, April 2, 1999, page B-2.)

14. On September 21, 1999, the French Ministry of Health approved the sale of the Gen-Probe blood screening tests in France. Gen-Probe anticipates approval of its tests for us in Australia in early 2000.

15. Gen-Probe has entered into an agreement with Chiron Corporation ("Chiron") of Emeryville, California, with respect to the development, manufacture, and distribution of blood

screening products. Gen-Probe is also a party to an agreement with Bayer Corporation ("Bayer") of Emeryville, California with respect to the development, manufacture, and distribution of clinical diagnostic products for the detection of HIV and hepatitis C, among other pathogens.

16. Gen-Probe anticipates that additional clinical trials in the United States of its HIV/HCV tests for use in blood screening and in clinical diagnostics will commence in the first part of 2000. Gen-Probe anticipates the conclusion of those clinical trials, and the initiation of commercial sales in the United States of kits containing its HIV/HCV blood screening test, during 2000.

17. All of the Gen-Probe products are manufactured in San Diego, California.

THE '338 PATENT

18. Gen-Probe is informed and believes that on or about May 12, 1998, the United States Patent and Trademark Office issued United States Patent No. 5,750,338 ("the '338 patent") based upon Patent Application No. 238,080 filed on May 3, 1994.

19. Gen-Probe is informed and believes that defendant Vysis claims to be the owner, by assignment, of the entire right, title and interest of the '338 patent. The claims of the '338 patent purport to relate to assays and probes for polynucleotide molecules such as DNA and RNA.

20. In early 1999, Vysis informed Gen-Probe that it believed that the '338 patent "applied" to Gen-Probe's NAT blood screening tests for HIV and HCV. Following further discussions and to avoid any complications in Gen-Probe's plans for commercial deployment of its NAT test kits, as of June 22, 1999 Gen-Probe obtained a license ("the License") from Vysis under the '338 patent. Gen-Probe also obtained options to the License for its relationships with Chiron and Bayer.

21. Under the terms of the License, Vysis requires Gen-Probe (and its allied parties if the options are exercised) to make significant financial payments to Vysis as royalties on the sale of any product covered by any valid claims of the '338 patent.

22. Notwithstanding the existence of the License, and as further alleged herein, Gen-Probe believes that the claims of '338 patent are invalid in all material respects. Furthermore, Gen-Probe believes that its NAT blood screening tests do not infringe any valid claim of the '338 patent.

As such, Gen-Probe disagrees with Vysis' contention that the claims of the '338 patent "apply" to Gen-Probe's activities and contemplated products. For these same reasons, Gen-Probe contends that it has no obligation to make any royalty payments to Vysis with respect to its present products and activities and any contemplated products and activities that Vysis may later claim infringe the claims of the '338 patent.

23. Gen-Probe has communicated to Vysis its belief that the claims of the '338 patent are invalid. In support of that belief, Gen-Probe has provided Vysis with information that demonstrates that the claims of the '338 patent are invalid. Gen-Probe has also advised Vysis of its belief that its NAT test kits for use in detecting HCV and HIV in the Nation's blood supply do not and will not infringe any valid claims of the '338 patent.

24. Notwithstanding its receipt of the foregoing information, Vysis persists in its assertion that the claims of the '338 patent are valid and enforceable and that Gen-Probe is obligated to make royalty payments in accordance with the terms of the License.

25. Based upon a long history of litigation between Gen-Probe and Vysis and its affiliates, Gen-Probe reasonably anticipates that should it fail to pay royalties pursuant to the License, Vysis will aggressively attempt to enforce its perceived rights under both the License and the '338 patent by terminating the License and by initiating litigation against Gen-Probe, its allied parties, and customers.

26. An actual case or controversy exists between Gen-Probe and Vysis concerning the validity and infringement of the '338 patent and Gen-Probe's rights and obligations under the License. The determination of the issues presented in this complaint will inure to the greater public benefit and good.

COUNT ONE

NON-INFRINGEMENT OF THE '338 PATENT

27. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

28. Gen-Probe's NAT test kits for use in detecting HCV and HIV in the Nation's blood supply do not and will not infringe any valid claims of the '338 patent.

COUNT TWO

INVALIDITY OF THE '338 PATENT

29. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

30. The claims of the '338 patent are invalid by reason of one or more provisions of Title 35 of the United States Code.

COUNT THREE

DECLARATORY RELIEF

31. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 26 of this complaint.

32. An actual controversy has arisen and now exists concerning the rights and obligations of Gen-Probe pursuant to the terms of the parties' License. Those disputes arise from and their resolution depends upon the federal patent laws.

33. Gen-Probe seeks a declaration of its rights and obligations under the License, particularly in light of the invalidity and non-infringement of the '338 patent and defendant's acts of unfair competition as alleged herein.

COUNT FOUR

UNFAIR COMPETITION

34. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 33 of this complaint.

35. Vysis knows or should know the underlying facts establishing the invalidity and/or unenforceability of the claims of the '338 patent. In continuing to enforce the claims of the '338 patent, Vysis has acted and continues to act unfairly, inequitably and in bad faith. In addition, Vysis' actions constitute unlawful, unfair or fraudulent business practices under California Business & Professions Code Sections 17200, *et seq.*

36. By reason of the aforementioned acts of unfair competition and unlawful, unfair and fraudulent business practices, Gen-Probe is entitled to damages, as established at time of trial,

restitution and injunctive relief.

COUNT FIVE

UNENFORCEABILITY OF THE '338 PATENT

37. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 36 of this complaint.

38. Applicants for patents have a general duty of candor and good faith in their dealings with the Patent and Trademark Office (the "Patent Office") and an affirmative obligation to disclose to the Patent Office all information that they know to be material to the examination of a pending application pursuant to 37 C.F.R. § 1.56. This duty extends to the applicants and their representatives, such as their attorneys, and all others associated with the prosecution, including every person who is substantively involved in the preparation or prosecution of the application.

39. Gen-Probe is informed and believes, and thereon alleges, that Vysis or its predecessors-in-interest and their agents (hereinafter collectively referred to as "the applicants") knowingly and willfully concealed and misrepresented material evidence during the prosecution of the '338 patent applications and that by such inequitable conduct, the '338 patent is unenforceable against Gen-Probe for the reasons that follow.

FACTS RELATED TO THE ABANDONMENT OF THE CLAIMED INVENTION OF NUCLEIC ACID AMPLIFICATION

40. On October 23, 1986, the applicants filed a patent application entitled "Target and Background Capture Methods and Apparatus for Affinity Assays." After filing, the Patent Office assigned that application the numerical designation, Serial No. 06/922,155 (the "'155 application"). Although, the '155 application purported to describe a technique for reversible target capture, it contained no disclosure of or claims to amplification techniques as claimed by Vysis in the '338 patent. The applicants identified Mark L. Collins as the sole inventor of the alleged inventions claimed in the '155 application.

41. On December 21, 1987, prior to substantive examination of the '155 application by the Patent Office, Vysis filed a Continuation-in-Part of the '155 application. The Patent Office assigned this Continuation-in-Part application Serial No. 07/136,920 (the "'920 application"). The

applicants entitled the '920 application "Target and Background Capture Methods with Amplification," and initially submitted claims in the '920 application to a method of nucleic acid amplification (claims 1-23), and a claim to an instrument for performing assays for target polynucleotides (claim 24).

42. In its initial examination of the '920 application, the Patent Office issued a restriction requirement because it deemed the claimed inventions of the amplification and instrument claims of the '920 application as distinct. In response to that restriction requirement, the applicants elected to proceed in the '920 application by prosecuting only the amplification claims (claims 1-23).

43. On July 20, 1990, following the applicants' election to proceed with only the amplification claims in the '920 application, the Patent Office issued an office action regarding that application by which it rejected all claims of the '920 application on prior art and other grounds of patentability. The Patent Office provided the applicants until October 20, 1990, with extensions available until January 20, 1991, to submit a substantive response to that office action.

44. Rather than prepare a substantive response to the July 20, 1990 office action, and in order to continue prosecuting claims to a method of nucleic acid amplification, on January 22, 1991, the applicants filed a continuing application from the '920 application. The Patent Office designated this continuing application as application Serial No. 07/644,967 (the "'967 application"). Concurrent with the filing of the '967 application, the applicants then expressly abandoned the '920 application.

45. On March 12, 1991, the Patent Office issued an office action for the '967 application by which it issued a final rejection of the claims submitted with that application. Pursuant to statute, the Patent Office provided the applicants with a shortened response period until June 12, 1992, with extensions available until September 12, 1992, to respond to this final rejection of the claims of the '967 application.

46. Again rather than prepare a substantive response to the March 12, 1992, office action, and in order to continue prosecuting claims to a method of nucleic acid amplification, on September 14, 1992, the applicants filed a continuation application to the '967 application. The

Patent Office designated this further continuation application Serial No. 07/944,505 (the "'505 application"). Consistent with continuation practice and rules, the applicants presented only claims to a method of nucleic acid amplification the '505 application, all other claims having been withdrawn by prior election. Concurrent with their filing of the '505 application, the applicants then expressly abandoned the '967 application.

47. On November 5, 1992, the Patent Office issued an office action for the '505 application by which it issued a final rejection of the claims submitted with that application. Pursuant to statute, the Patent Office provided the applicants with a shortened response period until February 5, 1993, with extensions available until May 5, 1993, to respond to this final rejection of the claims of the '505 application.

48. With the applicants' express knowledge and awareness of the requirement to respond to the November 5, 1992, office action within the statutorily required time and the further knowledge of the consequences of abandonment arising from any failure to respond within that required time, applicants intentionally elected not to respond to the office action.

49. Consistent with Patent Office rules and procedures, following the applicants' failure to respond to the November 5, 1992, office action, on June 16,1993, the Patent Office sent a formal notice of abandonment of the '505 application to the applicants. Again, however, consistent with the applicants' intentional decision not to respond to the office action, the applicants intentionally determined not to respond to the notice of abandonment.

FACTS RELATED TO THE PROSECUTION OF THE ALLEGED INSTRUMENT INVENTION

50. Gen-Probe is informed and believes, and thereon alleges, that the applicants intentionally failed to respond to the November 5, 1992, office action rejecting the claims of the '505 application and further intentionally failed to respond to the June 16, 1993 notice of abandonment as a result of their decision to abandon the alleged invention directed to a method of nucleic acid amplification originally elected for prosecution in the '920, '967 and '505 applications.

51. On January 31, 1991, consistent with the applicants' decision to acquiesce to the Patent Office's July 20, 1990, restriction requirement issued with respect to the distinct claimed inventions that applicants presented in the '920 application, the applicants filed a separate

application by which they elected to prosecute only instrument-related claims originally presented as claim 24 of the '920 application. The Patent Office assigned this instrument application Serial No. 07/648,468 (the "'468 application"). As originally filed and consistent with the restriction requirement, in the '468 application, the applicants submitted only claims directed to an instrument for performing assays for target polynucleotides. The applicants entitled the '468 application "Closed Vessel for Isolating Target Molecules and for Performing Amplification."

52. Through their '468 application, the applicants claimed priority of their instrument invention as a continuation-in-part application to the '920 and earlier '155 applications. However, applicants' claim to priority to the '920 and '155 applications was defective as it violated the requirement that the '468 application have been filed prior to the abandonment of the priority applications. In this case, although the applicants filed the '468 application on January 31, 1991, they intentionally abandoned the '920 application on January 22, 1991 and intentionally abandoned the '155 application on February 3, 1990. The applicants intentionally failed to disclose this lack of co-pendency of the '468 application during the prosecution of the '468 application.

53. The Patent Office initially rejected all the claims of the '468 application on prior art and other grounds of patentability in an office action mailed March 18, 1992. The Patent Office provided the applicants until June 18, 1992, with extensions available until September 18, 1992, to submit a substantive response to that office action.

54. Rather than prepare a substantive response to the March 18, 1992 office action, and in order to continue prosecuting claims to an instrument for performing assays for target polynucleotides, on September 17, 1992, the applicants filed a continuing application from the '468 application. The Patent Office designated this continuing application as application Serial No. 07/946,749 (the "'749 application"). Consistent with the restriction requirement originally issued in the '920 application, the applicants submitted only claims directed to an instrument for performing assays for target polynucleotides in the '749 application. Concurrent with the filing of the '749 application, the applicants then expressly abandoned the '468 application.

55. The Patent Office initially rejected all the claims of the '749 application on prior art and other grounds of patentability in an office action mailed March 22, 1993. The Patent Office

provided the applicants until June 22, 1993, with extensions available until September 22, 1993, to submit a substantive response to that office action.

56. Rather than prepare a substantive response to the March 22, 1993 office action, and in order to continue prosecuting claims to an instrument for performing assays for target polynucleotides, on September 21, 1993, the applicants filed a continuing application from the '749 application. The Patent Office designated this continuing application as application Serial No. 08/124,826 (the "'826 application"). Consistent with the restriction requirement originally issued in the '920 application, the applicants submitted only claims directed to an instrument for performing assays for target polynucleotides in the '826 application. Concurrent with the filing of the '826 application, the applicants then expressly abandoned the '749 application.

57. The Patent Office initially and finally rejected all the claims of the '826 application on prior art and other grounds of patentability in an office action mailed December 9, 1993. The Patent Office provided the applicants until March 9, 1994, with extensions available until June 9, 1994, to submit a substantive response to that office action.

58. Rather than prepare a substantive response to the December 9, 1993 office action, and in order to continue prosecuting claims to an instrument for performing assays for target polynucleotides, on June 8, 1994, the applicants filed a continuing application from the '826 application. The Patent Office designated this continuing application as application Serial No. 08/257,469 (the "'469 application"). Consistent with the restriction requirement originally issued in the '920 application, the applicants submitted only claims directed to an instrument for performing assays for target polynucleotides in the '469 application. Concurrent with the filing of the '469 application, the applicants then expressly abandoned the '826 application.

59. The Patent Office initially and finally rejected all the claims of the '469 application on prior art and other grounds of patentability in an office action mailed September 12, 1994. The Patent Office provided the applicants until December 12, 1994, with extensions available until March 12, 1995, to submit a substantive response to that office action.

60. Rather than prepare a substantive response to the December 12, 1994 office action, and in order to continue prosecuting claims to an instrument for performing assays for target

polynucleotides, on March 8, 1995, the applicants filed a continuing application from the '469 application. The Patent Office designated this continuing application as application Serial No. 08/400,657 (the "'657 application"). Consistent with the restriction requirement originally issued in the '920 application, the applicants submitted only claims directed to an instrument for performing assays for target polynucleotides in the '657 application. Concurrent with the filing of the '657 application, the applicants then expressly abandoned the '469 application.

61. The Patent Office initially and finally rejected all the claims of the '657 application on prior art and other grounds of patentability in an office action mailed April 25, 1995. The Patent Office provided the applicants until July 5, 1995, with extensions available until October 5, 1995, to submit a substantive response to that office action.

62. Rather than prepare a substantive response to the April 25, 1995 office action, on October 25, 1995, the applicants submitted a notice of appeal of the '657 application. Rather than file an appeal brief, and in order to continue prosecuting claims to an instrument for performing assays for target polynucleotides, on March 25, 1996, the applicants filed a continuing application from the '657 application. The Patent Office designated this continuing application as application Serial No. 08/622,491 (the "'491 application"). Consistent with the restriction requirement originally issued in the '920 application, the applicants submitted only claims directed to an instrument for performing assays for target polynucleotides in the '491 application. Concurrent with the filing of the '491 application, the applicants then expressly abandoned the '657 application.

APPLICANTS' EFFORTS TO OVERCOME THEIR INTENTIONAL ABANDONMENT OF THE '505 APPLICATION AND THEIR ALLEGED CLAIMS TO A METHOD OF AMPLIFICATION

63. Gen-Probe is informed and believes, and based thereon alleges, that sometime on or before May 3, 1994, the applicants determined to attempt to reverse their prior intentional abandonment of the alleged invention directed to a method of nucleic acid amplification. As a result of that determination, on May 3, 1994, fifteen months after they failed to respond to the shortened statutory response to the office action of November 5, 1993 and almost eleven months after they further failed to respond to the formal notice of abandonment, applicants attempted to

revive their '505 application by filing a formal petition to revive the '505 application. In that petition, the applicants misrepresented the fact concerning their prior intentional abandonment of the '505 application and claimed that they "unintentionally" failed to respond to the Patent Office. The applicants stated that "[t]he abandonment occurred as a result of the oversight of Applicants representative and was not intended by Applicants."

64. As set forth above, the applicants' claim of unintentional abandonment of the '505 was false. Gen-Probe is informed and believes, and based thereon alleges, that the applicants' failure to respond to the Patent Office's rejection of the claims of '505 application directed to the claimed invention of a method of nuclei acid amplification was intentional. Indeed, the applicants' intentional decision not to respond to the '505 office action was consistent with and driven by applicants' underlying decision to abandon the invention claimed in the '505 application.

65. On October 27, 1994, the Patent Office rendered a decision denying the applicants' petition to revive the '505 application. As the Patent Office explained, the '505 application became abandoned on February 6, 1993, when the applicants failed to respond to the office action of November 5, 1992. Because the petition to revive the '505 application was filed more than one year after the '505 application became abandoned, the petition was barred under 37 C.F.R. 1.137(b). Accordingly, the Patent Office refused to revive the '505 application under 37 C.F.R. 1.137(b).

66. The Patent Office informed the applicants that they might be able to revive the '505 application under the provisions of 37 C.F.R. 1.137(a). However, the Patent Office explained that "in view of the fact that this case has been abandoned for an inordinate period of time, petitioner must show diligence between the time of becoming aware of the abandonment of the above-identified application and the filing of a petition to revive."

67. The applicants declined to seek relief pursuant to 37 C.F.R. 1.137(a), thereby acquiescing to the Patent Office's determination that the '505 patent was abandoned on February 6, 1993.

68. Concurrent with their ultimately unsuccessful effort to revive the '505 application, on May 3, 1994, the applicants filed a new original application that the Patent Office designated as

Serial No. 08/238,080 (the "'080 application"), filed. In the '080 application, the applicants did not initially disclose to the Patent Office that the application was virtually identical to that they intentionally abandoned in the '505 application or of the fact of that abandonment. In addition, the applicants also failed initially to disclose the fact of their concurrent efforts to revive the '505 application. Furthermore, notwithstanding the fact that the applicants knew and intended that the '080 application should be treated as a new original application, applicants did not submit new oaths from the alleged inventors for the '080 application. The applicants also failed to disclose to the Patent Office that, as an original application, the claims of the '080 application were anticipated by the prior publication on August 23, 1989, of the applicants' own European application corresponding to the '920 application, European Application No. 88312135.2.

69. As a result of the applicants' intention to treat the '080 application as an original application and their concurrent failure to submit new oaths to support that application, on June 3, 1994, the Patent Office issued a notice to the applicants by which the Patent Office indicated that it had noted that the applicants had failed to file proper oaths or declarations for the '080 application.

70. In response to the Patent Office's notice to file the missing oaths necessary to support the '080 application, on February July 5, 1994, the applicants submitted a formal response to that notice by which response the applicants first disclosed the prior abandonment of the '505 application and petitioned the Patent Office to consider the '080 application as a continuation application to the '505 application. By that response, the applicants' concurrently petitioned the Patent Office to consider the '080 application as filed under 37 C.F.R. § 1.60 as a continuation of their previously abandoned '505 application. However, through this response and the petition incorporated therein, the applicants continued to misrepresent the prior abandonment of the '505 application and invention as "unintentional."

71. On October 27, 1994, the Patent Office formally dismissed the applicants' petition to revive the '505 application. The applicants did not disclose that decision to the branch of the Patent Office handling the applications' petition in the '080 application to treat the '080 application as a continuation application to the '505 application. In any event, however, on March 14, 1995, the Patent Office formally dismissed that petition as moot and declared that the '080 application

would be processed with a filing date of May 3, 1994.

72. The Patent Office decisions denying the applicants' petitions to revive the '505 application and to treat the '080 application as a continuation of the '505 created significant, indeed insurmountable, impediments to the applicants' desire to recant and reverse their earlier abandonment of the '505 application and the alleged invention consisting of the amplification method presented therein. Among other problems raised by those decisions, the applicants knew that unless they could manipulate the priority to which the '080 application was entitled, their own prior publications would constitute statutory bars to patentability.

APPLICANT'S EFFORTS TO FRAUDULENTLY MANUFACTURE CLAIMS OF PRIORITY FOR THE '080 APPLICATION

73. In light of the foregoing fatal impediments to patentability of the method claims presented in the '080 application, the applicants then proceeded to manufacture a scheme to undermine the Patent Office decisions denying their ability to claim priority for the '080 application back through the '505 application. As the first step in that scheme, on December 5, 1995, the applicants submitted a preliminary amendment in the '080 application in which they claimed, for the first time, that the '080 application was a divisional application to the '657 application that the applicants filed on March 8, 1995 to pursue the instrument claims and invention first claimed in the '468 application, as alleged in paragraph 60 of this Amended Complaint.

74. The applicants' efforts regarding and claim of priority of the '080 application to the '657 application were improper for several reasons. First, as indicated above, the applicants had previously elected to pursue only the instrument claims in the '657 application. As such, and without prior disclosure to or permission from the Patent Office, the applicants impermissibly "shift" their method claims back to the claim 24 of the '920 application, and subject to the restriction of July 20, 1990, in that application. As noted hereinabove, the applicants originally filed the chain of applications that included the '657 application in order to prosecute the claims directed to an invention regarding an instrument for performing assays for target polynucleotides, Second, the applicants' efforts to claim that the '080 application was a divisional application of the '657 application was additionally defective because the specification and claims of the '080 patent

are different from and not supported by the specification and claims of the '657 application.

75. However, in applicants' zeal to implement their inequitable scheme to overcome the Patent Office determination that the claims of the '080 application were only entitled to claim priority as of May 3, 1994, the applicants overlooked an even more significant defect in their effort to claim priority for the '080 application to the '657 application. Under the patent laws and regulations, an application is only entitled to claim priority to a prior application if such application was co-pending at some point in the "life" of the two applications. Yet, with respect to the applicants' scheme to advance the priority of the '080 application, their claim to priority of the '080 application to the '657 application violated this requirement of co-pendency because the applicants did not file the '657 application until March 8, 1995, nearly one year after the applicants filed the '080 application! The applicants failed to advise the Patent Office of this lack of co-pendency in their December 5, 1995, preliminary amendment. Gen-Probe is informed and believes, and based thereon alleges, that the applicants knew that the representation that the '080 application was a divisional of the '657 application was improper, and that the applicants made this representation with the intent of deceiving and misleading the Patent Office.

APPLICANTS' MISREPRESENTATIONS ABOUT MULLIS, U.S. PATENT NO. 4,683,202.

76. Despite their intentional failure to disclose the fatal defect in their claim of priority in the '080 application, the applicants continued to prosecute the claims of that application. During the course of that continued prosecution of the '080 application, the Patent Office rejected applicants' proposed claims to a method of nucleic acid amplification on the grounds of the disclosure of prior art that included the Mullis patent (U.S. Patent 4,683,202). In response, the applicants argued that the prior art did not teach or disclose purification of a target nucleic acid prior to amplification, yet, that argument was false. Specifically, in their December 5, 1995 Preliminary Amendment, the applicants made the following statements regarding the Mullis patent:

> Applicants submit the Examiner's conclusions is the product of an improper picking and choosing of selective disclosure from the cited references to obtain Applicants' invention and that when the references are considered for all that they teach the references do not disclose or suggest Applicants' invention. For example, while it is true that Mullis (U.S. No. 4,683,202) discloses DNA

amplification and some improved sensitivity and ability to isolate specific nucleoside sequences, Mullis also teaches away from Applicants' invention. Specifically, Mullis teaches:

> The present invention obviates the need for extensive purification of the product from a complicated biological mixture.

(Col. 2, lines 32-34). Mullis reaffirmed this teaching later in the disclosure:

> ***It is not necessary that the sequence to be amplified be present initially in a pure form; it may be a minor fraction of a complex mixture ... or a portion of a nucleic acid sequence due to a particular microorganism which organism might constitute only a very minor fraction of a particular biological sample.***

(***Col. 5, lines 49-56***). Plainly, Mullis teaches that the amplification method of his invention does not include purification before amplification and, in fact, does not require purification. Thus, Mullis teaches away from Applicants' invention.

12/5/95 Preliminary Amendment at p. 16 [emphasis added]. The applicants repeated this representation to the Patent Office regarding the teachings of Mullis in the Amendment filed on October 18, 1996, at pp. 11-12.

77. The paragraph cited by the applicants from the Mullis patent reads in whole:

> Any source of nucleic acid, in ***purified*** or nonpurified form, can be utilized as the starting nucleic acid or acids, provided it contains or is suspected of containing the specific nucleic acid sequence desired. Thus, the process may employ, for example, DNA or RNA, including ***messenger RNA***, which DNA or RNA may be single stranded or double stranded. In addition, a DNA-RNA hybrid which contains one strand of each may be utilized. A mixture of any of these nucleic acids may also be employed, or ***the nucleic acid produced from a previous amplification reaction*** herein using the same or different primers may be so utilized. The specific nucleic acid sequence to be amplified may be only a fraction of a larger molecule or ***can be present initially as a discrete molecule, so that the specific sequence constitutes the entire nucleic acid***. It is not necessary that the sequence to be amplified be present initially in a pure form; it may be a minor fraction of a complex mixture, such as a portion of the .beta.-globin gene contained in whole human DNA or a portion of

> nucleic acid sequence due to a particular microorganism which organism might constitute only a very minor fraction of a particular biological sample. The starting nucleic acid may contain more than one desired specific nucleic acid sequence which may be the same or different. Therefore, the present process is useful not only for producing large amounts of one specific nucleic acid sequence, but also for amplifying simultaneously more than one different specific nucleic acid sequence located on the same or different nucleic acid molecules.

(Col. 5, lines 34-63), emphasis added, underlined is the portion selectively cited by the applicants). Thus, contrary to the applicants' representation to the Patent Office, the omitted portion of the paragraph cited by the applicants expressly teaches that ***purification can and should be used*** with the amplification invention, thereby validating the Examiner's rejection.

78. In addition to the excluded portion of the paragraph of the Mullis patent, the very next paragraph in the Mullis patent states:

> The nucleic acid or acids may be obtained from any source, for example, from plasmids such as pBR322, from cloned DNA or RNA, or from natural DNA or RNA from any source, including bacteria, yeast, viruses, and higher organisms such as plants or animals. ***DNA or RNA may be extracted from blood, tissue material such as chorionic villi or amniotic cells by a variety of techniques such as that described by Maniatis et al., Molecular Cloning A Laboratory Manual (New York: Cold Spring Harbor Laboratory, 1982), pp. 280-281.***

(Col. 5, line 64-col. 6, line 6 [emphasis added]). Maniatis, et al., is a methods manual that teaches a variety of techniques for purifying RNA or DNA from blood, tissue or other cellular material. At pages 197-198 of Maniatis, et al., this reference teaches the purification of mRNA on a solid support using a probe. Thus, the very next paragraph of the Mullis patent following the selective citation by the applicants incorporates a disclosure of ***how*** to purify a sample prior to amplification. Gen-Probe is informed and believes, and based thereon alleges, that the applicants' knowingly and intentionally misrepresented the teachings of the Mullis reference to the United States Patent and Trademark Office. The applicants' selective removal of the first half of the cited paragraph that fully supported the Examiner's rejection based on Mullis and the following paragraph's implicit teaching of how to purify a sample prior to amplification evidence the knowing and intentional

nature of the applicants' misrepresentation of the Mullis reference.

APPLICANTS' MISREPRESENTATIONS IN THE REQUEST FOR CERTIFICATE OF CORRECTION FILED FOR THE '338 PATENT

79. On December 14, 1998, the applicants submitted a Request for Certificate of Correction for the '338 patent. Gen-Probe is further informed and believes, and based thereon alleges, that in this Request for Certificate of Correction the applicants represented to the U.S. Patent and Trademark Office that the '505 application was unintentionally abandoned.

80. Gen-Probe is informed and believes, and based thereon alleges, that the applicants made this representation knowing that the true facts were that the '505 application was intentionally abandoned.

81. In the December 14, 1998, Request for Certificate of Correction for the '338 patent, the applicants identified a fatal defect in the claimed priority for the '338 patent involving patent application Serial No. 07/648,468, and patent application Serial No. 07/136,920. By the December 14, 1998, Request for Certificate of Correction, the applicants attempted to cure that fatal defect by, in part, representing to the Patent Office that the applicants did not discover the fatal priority defect prior to the issuance of the '338 patent.

82. The applicants also represented in the Request for Certificate of Correction for the '338 patent that the mistakes for which correction was sought were of minor character, and resulted from errors made in good faith by the applicants.

83. Gen-Probe is informed and believes, and based thereon alleges, that through the aforementioned Certificate of Correction, the applicants knowingly and intentionally misrepresented its knowledge regarding this priority defect with the intent of deceiving the U.S. Patent and Trademark Office. In truth, the applicants were aware of the defect in its claim of priority for the '338 patent well before the issuance of the '338 patent. In addition, Gen-Probe is informed and believes, and based thereon alleges, that the applicants knew that the mistakes for which correction was sought were not of minor character, and did not resulted from errors made in good faith by the applicants, and intentionally misrepresented this to the Patent Office.

84. The applicants further represented in the Request for Certificate of Correction for

the '338 patent that the '338 patent was a continuation of the '826 application. However, the '338 patent could not be a continuation of the '826 application, because the disclosure of the '338 patent was not identical to the disclosure of the '826 application.

85. Gen-Probe is informed and believes, and based thereon alleges, that the applicants knew that the '338 patent could not be a continuation of the '826 application, and that through the aforementioned Certificate of Correction, the applicants knowingly and intentionally misrepresented its knowledge with the intent of deceiving the U.S. Patent and Trademark Office.

APPLICANTS' MISREPRESENTATION IN THEIR PETITION UNDER 37 C.F.R. §1.182

86. On December 14, 1998, the applicants filed a petition with the Patent Office under 37 C.F.R. § 1.182 to amend the claimed priority stated in application Serial No. 08/124,826 (the "'826 application") so as to attempt to cure further fatal defects in the priority claim for the '338 patent. At the time of such petition, however, the applicants had previously intentionally abandoned the '826 application.

87. In order to overcome the impediment to its effort to cure the fatal defect in the claim of priority for the '338 patent arising in the '826 application, the applicants argued in its petition to amend the '826 application that an intentionally abandoned application could be amended after abandonment. Gen-Probe is informed and believes, and based thereon alleges, that the applicants misrepresented legal authority to the U.S. Patent and Trademark Office. Gen-Probe is informed and believes, and based thereon alleges, that the applicants' knew that the legal authority it presented to the Patent Office to support its petition to amend the '826 application and cure the otherwise fatal priority defect in the '338 patent did not stand for the proffered proposition and that the applicants knowingly misrepresented this legal authority to the U.S. Patent and Trademark Office with the intent to deceive the Patent Office.

APPLICANTS' FAILURE TO DISCLOSE ALL ART KNOWN TO IT DURING THE PROSECUTION OF THE '338 PATENT

88. During the course of its prosecution of the claims that ultimately issued in the '338 patent, the applicants concurrently presented counterpart patent applications and patent claims to international and foreign patent offices. During the course of the examination and prosecution of

those counterpart applications and patent claims, the European Patent Office, for one, identified and disclosed to the applicants prior art material to the prosecution of the '338 patent claims that was not before or considered by the United States Patent and Trademark Office in the examination of the '338 patent. For example, among this prior art of record in the European Patent Office proceedings but not in the United States Patent Office was the following: EP-A-0200362 (Cetus Corp.); EP-A-0265244 (Amoco Corp.); EP-A-0154505 (Ortho Diagnostic Systems, Inc.); WO-A-8605815 (Genetics Int'l Inc.); WO-A-8701730 (Yale Univ.).

89. Notwithstanding the applicants' duty to disclose all material information to the Patent Office, the applicants failed to disclose the foregoing prior art to the Patent Office. In addition, upon filing the application which led to the issuance of the '338 patent, the applicants did not submit a Form 1449, citing all known material art to the Patent Office, as required to ensure that all known material art is considered by the Patent Office. Gen-Probe is informed and believes, and based thereon alleges, that the applicants knowingly and intentionally failed to submit a Form 1449 and concurrently failed to apprise the Patent Office of prior art identified in the European Patent Office proceedings in order to deceive the Patent Office and prevent it from considering all relevant prior art.

COUNT SIX

UNENFORCEABILITY OF THE '338 PATENT DUE TO LACHES.

90. Gen-Probe repeats, repleads and incorporates herein the allegations of paragraphs 1 through 89 of this complaint.

91. Gen-Probe is informed and believes, and based thereon alleges, that the applicants intentionally, unreasonably, and inexcusably delayed in the prosecution of the invention claimed in the '338 patent, and that Gen-Probe was prejudiced by this delay. Accordingly, the '338 patent is unenforceable against Gen-Probe due to laches.

WHEREFORE, Gen-Probe prays as follows:

1. For declarations:

a. That Gen-Probe's products do not and will not infringe any valid claims of '338 patent;

b. That the claims of the '338 patent are invalid;

c. That the claims of the '338 patent are unenforceable; and

d. Of Gen-Probe's rights and obligations under the License;

2. For a preliminary and permanent injunction enjoining and restraining defendant, its respective officers, agents, servants, employees and attorneys, and all persons acting in concert with them, and each of them:

a. From making any claims to any person or entity that Gen-Probe's products infringe the '338 patent;

b. From interfering with, or threatening to interfere with the manufacture, sale, license, or use of Gen-Probe's products by Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns, and others; and

c. From instituting or prosecuting any lawsuit or proceeding, placing in issue the right of Gen-Probe, its allied parties, distributors, customers, licensees, successors or assigns, and others to make, use or sell Gen-Probe's products;

3. For recovery of Gen-Probe's damages, as proven at time of trial, and restitution of any sums by which Vysis has been unjustly enriched;

4. For recovery of Gen-Probe's attorneys' fees and costs of suit incurred herein; and

5. For such other and further relief as the Court may deem just and proper.

Dated: January __, 2001

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By: _____
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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED, Plaintiff, v. VYSIS, INC., Defendant.	No. 99cv2668 H (AJB) **NOTICE OF LODGMENT OF CASE AUTHORITY NOT IN OFFICIAL REPORTER SYSTEM IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT** Date: February 20, 2001 Time: 10:30 a.m. Dept: Courtroom 1

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that Plaintiff Gen-Probe Incorporated hereby lodges the following cases which do not appear in the official Federal Reporter system, but which are cited in support of its Motion for Leave to File a Second Amended Complaint:

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EXHIBIT 1: *Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation, Limited Partnership*, 2000 WL 1300430 (Fed. Cir. Sept. 1, 2000).

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EXHIBIT 1

2000 WL 1300430 (Table)
56 U.S.P.Q.2d 1381
Unpublished Disposition
(Cite as: 2000 WL 1300430 (Fed.Cir.))

United States Court of Appeals, Federal Circuit.

SYMBOL TECHNOLOGIES, INC., Accu-Sort Systems, Inc., Intermec Technologies Corporation, Metrologic Instruments, Inc., PSC Inc., Teklogix Corporation, Zebra Technologies Corporation, and Cognex Corporation, Plaintiffs-Petitioners,
v.
LEMELSON MEDICAL, EDUCATION & RESEARCH FOUNDATION, LIMITED PARTNERSHIP,
Defendant-Respondent.

No. 626.

Sept. 1, 2000.

On Petition for Permission to Appeal.

Before MICHEL, RADER, and SCHALL, Circuit Judges.

ORDER

MICHEL, Circuit Judge.

***1** Symbol Technologies, Inc. et al. (Symbol) petition for permission to appeal, pursuant to 28 U.S.C. § 1292(b), (c)(1), an order certified by the United States District Court for the District of Nevada. Lemelson Medical, Education, & Research Foundation, Limited Partnership (Lemelson) opposes. National Retail Federation moves for leave to file an amicus curiae brief in support of granting the petition, with brief attached. Lemelson opposes.

Briefly, this declaratory judgment action involves Lemelson patents related to bar code technology. The patents, which contain identical written descriptions and drawings, are based on a chain of continuing and divisional applications and may be entitled to a priority date in the mid 1950s. Lemelson moved to dismiss Symbol's defense, asserted in the fourth count of Symbol's complaint, that the equitable doctrine of laches in patent prosecution could be applied. The district court granted the motion to dismiss stating:

> [In Ford] the Honorable Lloyd D. George ... held that "Lemelson's use of the continuation applications process may have exploited an open area of patent practice, [but] the court should not intervene in equity to regulate what Congress has not." It is therefor improper to introduce the equitable doctrine of laches into the statutory scheme of continuation practice.

The district court subsequently certified its order dismissing Symbol's "laches in prosecution" claim as involving a controlling question of law as to which there was a substantial ground for difference of opinion and that an immediate appeal from such order could materially advance the ultimate termination of the litigation. [FN*]

> FN* Symbol asserts that the controlling question of law is:
> As a matter of law, can the equitable doctrine of laches ever apply to bar enforcement of patent claims which were first presented to the Patent Office for examination after an unreasonable and unexplained delay that causes injury to an alleged infringer and others?

Symbol states that this court has not definitively determined whether laches in prosecution can be a defense to an infringement action. Symbol also states that Lemelson has sued "hundreds of defendants" based on its bar code patents. Symbol and the amicus forcefully urge the court to grant Symbol's petition.

This court has complete discretion in determining whether to grant or deny a petition for permission to appeal. In re Convertible Rowing Exerciser Patent Litigation, 903 F.2d 822 (Fed.Cir.1990). We determine in our discretion to grant Symbol's petition, in part because the issue affects not only this case, but many other cases as well.

Accordingly,

IT IS ORDERED THAT:

(1) Symbol's petition for permission to appeal is granted.

(2) National Retail Federation's motion for leave to file an amicus brief in support of the petition is granted.

END OF DOCUMENT

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. 99cv2668 H (AJB)

PROOF OF PERSONAL SERVICE

Date: February 20, 2001
Time: 10:30 a.m.
Dept.: Courtroom 1

PROOF OF PERSONAL SERVICE

I, _____, hereby declare:

I am employed in the City of San Diego, County of San Diego, California; I am over the age of eighteen years and not a party to the within action; my business address is Express Network, 401 West A Street, Suite 190, San Diego, California 92101.

On January 19, 2001, I served the within **NOTICE OF MOTION AND MOTION OF GEN-PROBE INCORPORATED FOR LEAVE TO FILE SECOND AMENDED COMPLAINT; MEMORANDUM POINTS AND AUTHORITIES IN SUPPORT IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT; DECLARATION OF STEPHEN P. SWINTON IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT; NOTICE OF LODGMENT OF CASE AUTHORITY NOT IN OFFICIAL REPORTER SYSTEM IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT** on the interested parties in this action by personally hand delivering a copy of said document(s) to the address(es) listed below:

John H. L'Estrange, Jr. Esq.
Wright and L'Estrange
701 B Street, Suite 1550
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Attorneys for Vysis, Inc.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on January 19, 2001.

_____
(signature)

_____
(print name)

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Attorneys for Plaintiff,
GEN-PROBE INCORPORATED

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

No. 99cv2668 H (AJB)

PROOF OF SERVICE

Date: February 20, 2001
Time: 10:30 a.m.
Dept.: Courtroom 1

PROOF OF SERVICE (FEDERAL EXPRESS)

I, Alison J. Lyman, hereby declare:

I am employed in the City of San Diego, County of San Diego, California in the office of a member of the bar of the court in which the within action is pending at whose direction the following service was made. I am over the age of eighteen years and not a party to the within action. My business address is Cooley Godward LLP, 4365 Executive Drive, Suite 1100, San Diego, California 92121-2128. I am personally and readily familiar with the business practice of Cooley Godward LLP for collection and processing of notices and other papers to be sent by overnight delivery service by Federal Express. Pursuant to that business practice, envelopes and packages are placed for collection at designated stations and in the ordinary course of business are that same day deposited in a box or other facility regularly maintained by such express service carrier or delivered to an authorized courier or driver authorized by such express service carrier to receive documents, in an envelope or package designated by such express service carrier, with delivery fees paid or provided for.

On January 19, 2001, I served: **NOTICE OF MOTION AND MOTION OF GEN-PROBE INCORPORATED FOR LEAVE TO FILE SECOND AMENDED COMPLAINT; MEMORANDUM POINTS AND AUTHORITIES IN SUPPORT IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT ; DECLARATION OF STEPHEN P. SWINTON IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT; NOTICE OF LODGMENT OF CASE AUTHORITY NOT IN OFFICIAL REPORTER SYSTEM IN SUPPORT OF GEN-PROBE INCORPORATED'S MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT** on the interested parties in this action by placing a true copy thereof, on the above date, enclosed in a sealed envelope, at a station designated for collection and processing of envelopes and packages for overnight delivery service by Federal Express as part of the ordinary business practice of Cooley Godward LLP described above, addressed as follows:

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I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and that this declaration was executed on January 19, 2001, at San Diego, California.

Alison J. Lyman